Exhibit A

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

DECLARATION OF MANSOOR M. AMIJI, PH.D. IN SUPPORT OF BLUEWILLOW'S MOTION FOR SUMMARY JUDGMENT

I, Dr. Mansoor M. Amiji, declare as follows:

1. My name is Mansoor M. Amiji. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned matter. I am knowledgeable about the matters set forth in this Declaration, and am submitting this Declaration on behalf of BlueWillow in support of its Motion for Summary Judgment.

2. Attached as Exhibit 1 is a true and correct copy of my Opening Expert Report on Invalidity, which I signed on June 27, 2022. Exhibit 1 contains my technical expert opinions and analysis regarding invalidity of U.S. Patent No. 8,163,802 ("the '802 Patent").

3. Attached as Exhibit 2 is a true and correct copy of my Responsive Expert Report on Non-Infringement, which I signed on August 15, 2022. Exhibit 2 contains my technical expert opinions and analysis regarding non-infringement of the '802 Patent.

4. Attached as Exhibit 3 is a true and correct copy of my Reply Expert Report on Invalidity, which I signed on September 29, 2022. Exhibit 3 contains my technical expert opinions and analysis regarding invalidity of the '802 Patent.

5. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 20, 2023

Mansoor M. Amiji, Ph.D.

EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

OPENING EXPERT REPORT OF MANSOOR M. AMIJI, PH.D. ON INVALIDITY

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I, Dr. Mansoor M. Amiji, submit this Opening Report as follows:

1. My name is Mansoor M. Amiji.

2. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned district court patent litigation case, with case number 2:21-cv-10312-SJM-RSW. I am being compensated for my time in connection with this litigation at my standard consulting rate of $900 per hour. My compensation is not affected by the outcome of this matter.

3. I have been informed that Trutek has accused BlueWillow of infringing claims 1, 2, 6 and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent") and have been asked to provide my opinions regarding whether claims 1, 2, 6, and 7 (the "Challenged Claims") of the '802 Patent are invalid. My analysis and opinions provided herein are limited to the Challenged Claims, and I reserve the right to amend and/or update my analysis and opinions should Trutek assert additional claims in this litigation.

4. This report sets forth the opinions that I have formed based on the information available to me as of the date below. The opinions and fact set forth in this report are based upon information and my analysis of the asserted patent, the prior art, the state of the art at the time of the invention, as well as my knowledge and experience in the relevant field. It is my understanding that expert

discovery is ongoing. I reserve the right to supplement or amend this report based on additional information made available to me, including in light of any expert reports or other responses to the subject matter addressed herein.

5. I expect to be called to testify at trial in the above-captioned action. If called upon, I am prepared to testify about my background, qualifications, and experience, as well as about the issues set forth in this report. If I am called upon to testify at trial, I may rely on exhibits and/or visual aids to demonstrate the bases for my opinions. I have not yet prepared any such exhibits or visual aids. I also reserve the right to provide a tutorial relating to the general topics contained in this report.

6. For the purposes of my Opening Report, I have been asked to assume that the priority date of the alleged invention recited in the Trutek '802 Patent is July 7, 2008 (hereinafter "Priority Date").

7. I am not currently and have not at any time in the past been an employee of BlueWillow. I have no financial interest in BlueWillow.

I. QUALIFICATIONS AND EXPERIENCE

8. I am an expert in the field of pharmaceutical sciences and drug formulation development and characterization. Specifically, I specialize in drug formulation development and targeted delivery of therapeutics, and I have been an

expert in this field since prior to July 7, 2008. I have relied upon my training, knowledge, and experience in the relevant art to form my opinions.

9. In 1988, I graduated with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, I received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University, under the supervision of Professor Kinam Park. My dissertation focused on biomaterials and water-soluble polymers. During my graduate studies at Purdue University, I took several pharmaceutics courses and had hands-on training in pharmaceutical formulation development and characterization.

10. After receiving my Ph.D. in 1992, I worked as a Senior Research Scientist for Columbia Research Laboratories (CRL) in Madison, Wisconsin. At CRL, I worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces.

11. I am currently the University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. I am also jointly appointed as a Professor of Chemical Engineering in the College of Engineering at Northeastern University. I am also currently an Affiliate Faculty Member in the

Department of Biomedical Engineering at Northeastern University. I have taught and carried out research in pharmaceutical sciences at Northeastern University since 1993, and from 2010 to 2016, I served as the Chairman of the Department of Pharmaceutical Sciences. In 2000, I was a Visiting Research Scholar in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT) in Cambridge, Massachusetts, in the laboratory of Professor Robert Langer.

12. As a tenured faculty member at Northeastern University, I have over 29 years of experience in teaching drug formulations to both graduate and undergraduate students. In theory and laboratory courses that I have taught and continue to teach, I extensively cover the manufacturing and composition of pharmaceutical formulations, delivery systems and pharmacokinetics. I also serve as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

13. I lecture extensively on various topics at the leading edge of modern pharmaceutical sciences, and I regularly attend numerous worldwide pharmaceutical conferences. I have been an invited speaker at national and international scientific conferences.

14. Over the course of my career I have published extensively and am ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. I have coauthored over 60 book chapters and more than 350 peer

reviewed scientific articles. I am also an inventor on several issued United States patents. The topics of these materials including the design and development of pharmaceutical dosage forms, pharmacokinetics, drug metabolism, dose delivery and controlled research systems and the use/formulation of related excipients and methods. I have been involved in and consulted on multiple projects over the years both in industry and academia about the aforementioned topics. To that end, I have taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics.

15. I have served as a grant reviewer for the National Institutes of Health, the Department of Defense, the United States Department of Agriculture, and the American Chemical Society. I am a member of several professional and industrial societies, including the American Association of Pharmaceutical Sciences (AAPS) and the Controlled Release Society (CRS), and have participated as a reviewer for more than 50 scientific journals.

16. I have also received a number of professional awards and honors, including the Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology in 2006; a Fellowship and Meritorious Manuscript Award from the AAPS in 2007; the Tsuneji Nagai Award from the CRS in 2012; the Northeastern University School of Pharmacy Distinguished Alumni

Award in 2016; and Purdue University College of Pharmacy Distinguished Alumni Award in 2019. Over the course of my career, I have advised numerous post-doctoral associates, doctoral students, master's students, visiting scientists, and research fellows.

17. I am a founder and scientific advisor to many pharmaceutical companies, including Nemucore Medical Innovations and Targagenix, Inc., which have licensed our patents on lipid-based drug delivery systems and is in the process of developing commercial products.

18. I was appointed as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2007 and served as a long-term member of the Association. I am also a Fellow of the Controlled Release Society (CRS) since 2014 and serve on the Scientific Advisory Board of the CRS. I have also served as a permanent member of the National Institutes of Health's grant review panel and many other public funding agencies in the U.S. and across the world. I am an Editor of the journal Drug Delivery and Translational Research and Associate Editor of several peer-reviewed journals and on the editorial board of about a half dozen other scientific journals.

19. Additional details concerning my background, training and experience are contained in my current *Curriculum Vitae*, attached as Exhibit 2.

20. Based on my education, training, and experience, including my research expertise in pharmaceutical product development and drug formulation development of over 29 years, including in the July 7, 2008 time frame, I am qualified to provide technical analysis and opinions regarding the subject matter of this case and the '802 Patent.

21. The matters in which I have testified in the past four years include:

- *iCeutica Private, LTD et al. v. Lupin Limited et al.*, C.A. No. 1:14-cv-01515-SLR-SRF (D. Del.)
- *Mylan Pharmaceuticals Inc. v. Allergan, Inc.*, C.A. No. IPR2016-01127, -1128, -1129, -1130, -1131, -1132 (PTAB)
- *Lipocine, Inc. v. Clarus Therapeutics, Inc.*, Patent Interference No. 106,045 (McK)
- Cadence Pharmaceuticals Inc., et al. v. InnoPharma Licensing LLC, et al., C.A. No. 1:14-cv-01225-LPS (D. Del.)
- *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, C.A. No. 2:2015-cv-06934 (D.N.J.)
- R*eckitt Benckiser LLC v. Aurobindo Pharma Limited*, C.A. No. 14-cv-1203-LPS (D. Del.)
- *AMAG Pharmaceuticals, Inc. v. Sandoz, Inc.*, C.A. No. 16-1508-PGS-LHG (D.N.J.)
- *Alcon Research, Ltd. v. Watson Laboratories. Inc.*, C.A. No. 16-129-LPS-SRF (D. Del.)
- *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*, C.A. No. 16-988-LPS (D. Del)
- *Almirall, LLC v. Taro Pharmaceutical Industries Ltd.*, C.A. No. 17-663-JFB-SRF (D. Del.)
- *Galderma Labs. LP v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 17-1783-RGA (D. Del.)
- *FWK Holdings LLC v. Shire PLC et al.*, C.A. No. 16-cv-12653-ADB (Lead) and No. 17-cv-10050-ADB (Consol.) (D. Mass.)
- *Impax Laboratories, Inc., v. Zydus Pharmaceuticals Inc & Cadilla Healthcare*, C.A. No. 17-cv-13476 (SRC)(CLW) (D.N.J)

- *Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.*, C.A. No. 18-cv-00823 (CFC) (D. Del.)
- *Vifor Fresenius Medical Care Renal Pharma Ltd. et al v. Lupin Atlantis Holdings SA et al*, C.A. No. 18-cv-00390 (MN) (D. Del.)
- *Pharmacyclics, et al., v. Cipla, et al.*, C.A. No. 1:18-cv-00192-CFC (Consol.) (D. Del.)
- *Lipocene, Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 1:19-cv-622-WCB (D. Del.)
- *Thorne Labs v Trustees of Dartmouth*, C.A. No. IPR2021-00268 (PTAB).

22. Based on my training, teaching, consulting, and research expertise in the pharmaceutical product development and drug delivery over the last 29 years, I am qualified to serve as an expert witness for this lawsuit.

II. MATERIALS AND OTHER INFORMATION CONSIDERED

23. In forming the opinions expressed in this report, I relied upon my education and experience in the relevant field of the art, and have considered the viewpoint of a person having ordinary skill in the relevant art as of the Priority Date of the ’802 Patent.

24. I have considered the materials referenced herein, including the ’802 Patent (Exhibit 1), the file history of the ’802 Patent (Exhibit 34), and have also considered the prior art references listed in the table below:

Exhibit	Description	Date of Public Availability
3	United States Patent Application Publication No. 2006/0163149 A1 (“Wadstrom”)	Published on July 27, 2006 and claiming priority to a provisional application filed June 13, 2003

Exhibit	Description	Date of Public Availability
4	United States Patent Application Publication No. 2004/0071757 A1 ("Rolf")	Published on April 15, 2004 and claiming priority to a provisional application filed November 20, 2001
5	United States Patent No. 5,468,488 ("Wahi '488")	Filed June 24, 1993 and issued on November 21, 1995
6	United States Patent No. 5,674,481 ("Wahi '481")	Filed November 20, 1995, claiming priority to a provisional application filed June 24, 1993, and issued on October 7, 1997
7	United States Patent Application Publication No. 2007/0243237 A1 ("Khaled")	Published on October 18, 2007, application filed on April 14, 2006
8	United States Patent No. 6,559,189 ("Baker '189")	Filed June 25, 2001, and issued on May 6, 2003
9	United States Patent Application Publication No. 2009/0143476A1 ("Baker '476")	Published on June 4, 2009 and claiming priority to a parent application filed on June 25, 2002
10	United States Patent No. 10,138,279 ("Baker '279")	Filed April 13, 2007, claiming priority to a provisional application filed April 13, 2006, and issued on November 27, 2018
11	United States Patent No. 6,635,676 ("Baker '676")	Filed September 27, 2001, and issued on October 21, 2003
12	United States Patent No. 6,531,142 ("Rabe")	Filed July 31, 2000, issued March 11, 2003
13	United States Patent Application Publication No. 2002/0006961 A1 ("Katz")	Published on January 17, 2002, application filed on May 1, 2001
14	United States Patent Application Publication No. 2003/0161790 A1 ("Wahi '790")	Published on August 28, 2003, application filed February 25, 2002
15	*Final Report on the Safety Assessment of Polyquaternium- 10*, Journal	Publically available as a publication at least as early as 1988

Exhibit	Description	Date of Public Availability
	of the American College of Toxicology (Vol. 7, No. 3, 1988)	
16	Patrick J. Sinko, *Martin's Physical Pharmacy and Pharmaceutical Sciences* (5th Ed. 2006) ("Martin's")	Publically available as a publication at least as early as 2006
17	*Final Report on the Safety Assessment of Benzalkonium Chloride,* Journal of the American College of Toxicology (Vol. 8, No. 4, 1989) ("Liebert")	Publically available as a publication at least as early as 1989
18	Rutala *et al., Guideline for Disinfection and Sterilization in Healthcare Facilities (2008)*	Publically available as a publication at least as early as 2008
19	Jean-Yves Maillard, *Antimicrobial biocides in the healthcare environment: efficacy, usage, policies, and perceived problems (2005)*	Publically available as a publication at least as early as 2005
20	Seymour S. Block, *Disinfection, Sterilization, and Preservation (1991)*	Publically available as a publication at least as early as 1991
21	Michael Szycher, *High Performance Biomaterials: A Comprehensive Guide to Medical and Pharmaceutical Applications (1991)*	Publically available as a publication at least as early as 1991
22	Remington, *The Science and Practice of Pharmacy (21st Ed. 2006)*	Publically available as a publication at least as early as 2006

Exhibit	Description	Date of Public Availability
23	Michael Ash and Irene Ash, *Chemical Tradename Dictionary (1993)*	Publically available as a publication at least as early as 1993
24	Moore *et al.*, *Microbiological Standards for Nasal Solutions, Journal of Applied Bacteriology (1976)*	Publically available as a publication at least as early as 1976
25	Bernstein, *Is the use of benzalkonium chloride as a preservative for nasal formulations a safety concern? A cautionary note based on compromised mucociliary transport (2000)*	Publically available as a publication at least as early as 2000
26	Nick Jones, *The nose and paranasal sinuses physiology and anatomy (2001)*	Publically available as a publication at least as early as 2001
27	Donald F. Procter and G. Kenneth Adams, III, *Physiology and Pharmacology of Nasal Function and Mucus Secretion (1976)*	Publically available as a publication at least as early as 1976
28	H. E. Junginger, *Drug Targeting and Delivery: Concepts in dosage form design (1992)*	Publically available as a publication at least as early as 2000
29	Veldman *et al.*, *New Frontiers in Immunobiology (2000)*	Publically available as a publication at least as early as 2000
30	Jin-Hwa Lee and Chang-Yu Wu, *Evaluation of the Performance of Iodine-*	

Exhibit	Description	Date of Public Availability
	Treated Biocide Filters Challenged with Bacterial Spores and Viruses, Final Report (Nov. 2006)	Publically available as a publication at least as early as November 2006
31	Rowe *et al.*, *Handbook of Pharmaceutical Excipients* (5th Ed. 2006)	Publically available as a publication at least as early as 2006
32	Barel et. al, *Handbook of Cosmetic Science and Technology* (2001)	Publically available as a publication at least as early as 2001
33	United States Patent Application Publication No. 2007/0134302 A1	Published on June 14, 2007, application filed December 13, 2005

25. I understand that none of these references were before the Patent Office during prosecution of the '802 Patent except "Wahi '488" and "Wahi '481."

26. The references listed in paragraph 24 above are prior art to the '802 Patent. The Wadstrom, Rolf, Baker '476, Katz, Khaled, and Wahi '790 applications were filed in the United States before the Priority Date of July 7, 2008, and all except Baker '476 were published before that Priority Date. The Wahi '481, Wahi '488, Baker '676, Baker '189, and Rabe patents issued more than one year before the Priority Date of July 7, 2008, and the Baker '279 patent was filed in the United Sates before the Priority Date of July 7, 2008.

27. With regard to the Handbook of Pharmaceutical Excipients (Ex. 31) and Remington's The Science and Practice of Pharmacy (Ex. 22), I am personally

familiar with and consulted these references at multiple times during my education and career, including prior to July 7, 2008.

28. The Handbook of Cosmetic Science and Technology (Ex. 32) is a leading textbook that discusses the various excipients that are disclosed in the '802 Patent. It is a standard reference textbook that is used by formulation scientists and a person of ordinary skill in the art would rely on it. Specifically, the Handbook provides a listing of the different types of excipients such as antibacterials and preservatives, hydrating substances (humectants), skin feel agents, and surfactants, among many others. A handbook relating to cosmetics is relevant to formulating the products disclosed in the '802 Patent as I understand that Trutek's products are considered cosmetics given that they did not go through the Federal Drug Administration drug approval process.

29. Based on my review of the remaining references listed in paragraph 24, I have found them to be authoritative and representative of the knowledge of a person of ordinary skill in the art at the time of their publication.

III. UNDERSTANDING OF PATENT LAW

30. I am not an attorney. For purposes of this report, I have been informed about certain aspects of the law that are relevant to my opinions, as described below.

A. Claim Construction

31. I have been informed that a claim must be construed under the *Phillips* standard. Under that standard, words of a claim are given their plain and ordinary meaning as understood by person of ordinary skill in the art at the time of invention, in light of the specification and prosecution history, unless those sources show an intent to depart from such meaning, as well as pertinent evidence extrinsic to the patent. For the purposes of this Opening Report, I applied the plain and ordinary meaning of each term to a person of ordinary skill in art ("POSA") at the time of the alleged invention unless explicitly stated otherwise. I understand that the parties have not yet exchanged claim construction positions and that the Court has not yet construed any of the claim terms of the ’802 Patent. I reserve the right to amend and/or update my analysis and opinions provided herein to the extent that any party offers a different claim construction and/or to the extent that the Court construes any such claim terms.

B. Obviousness

32. I have been informed and understand that a patent claim can be considered to have been obvious to person of ordinary skill in the art at the time the application was filed. This means that, even if all of the requirements of a claim are not found in a single prior art reference, the claim is not patentable if the differences between the subject matter in the prior art and the subject matter in the

claim would have been obvious to a person of ordinary skill in the art at the time the application was filed.

33. I have been informed and understand that a determination of whether a claim would have been obvious should be based upon several factors, including, among others:

- the level of ordinary skill in the art at the time the application was filed;
- the scope and content of the prior art; and
- what differences, if any, existed between the claimed invention and the prior art.

34. I have been informed and understand that the teachings of two or more references may be combined in the same way as disclosed in the claims, if such a combination would have been obvious to a person of ordinary skill in the art. In determining whether a combination based on either a single reference or multiple references would have been obvious, it is appropriate to consider at least the following factors:

- whether the teachings of the prior art references disclose known concepts combined in familiar ways, which, when combined, would yield predictable results;
- whether a person of ordinary skill in the art could implement a predictable variation, and would see the benefit of doing so;

- whether the claimed elements represent one of a limited number of known design choices, and would have a reasonable expectation of success by a person of ordinary skill in the art;
- whether a person of ordinary skill in the art would have recognized a reason to combine known elements in the manner described in the claim;
- whether there is some teaching or suggestion in the prior art to make the modification or combination of elements claimed in the patent; and
- whether the innovation applies a known technique that had been used to improve a similar device or method in a similar way.

35. I understand that a person of ordinary skill in the art has ordinary creativity, and is not an automaton.

36. I understand that in considering obviousness, it is important not to determine obviousness using the benefit of hindsight derived from the patent being considered.

37. I understand that prior art to the ’802 Patent includes patents and printed publications in the relevant art that predate the Priority Date of the ’802 Patent.

38. I understand that certain factors—often called “secondary considerations”—may support or rebut an assertion of obviousness of a claim. I

understand that such secondary considerations include, among other things, commercial success of the alleged invention, skepticism of those having ordinary skill in the art at the time of the alleged invention, unexpected results of the alleged invention, any long-felt but unsolved need in the art that was satisfied by the alleged invention, the failure of others to make the alleged invention, praise of the alleged invention by those having ordinary skill in the art, and copying of the alleged invention by others in the field. I further understand that there must be a nexus—a connection—between any such secondary considerations and the alleged invention. I also understand that contemporaneous and independent invention by others is a secondary consideration tending to show obviousness.

C. Anticipation

39. I understand that a patent claim is invalid if it is anticipated by a single item of prior art. I understand that an anticipation analysis involves two steps. First, the patent claims are construed to ascertain their scope. Second, each construed asserted claim is compared to the prior art reference on an element-by-element basis. If the prior art reference discloses or contains each and every element of the claimed invention, either expressly or inherently, then it anticipates the claim.

40. I understand that anticipation by inherent disclosure is appropriate only when a prior art reference necessarily includes or discloses the unstated claim element. I am also informed that the discovery of a new or previously unreported

or unappreciated property of a prior art composition, or of a scientific explanation for how a prior art composition operates, does not make the prior art composition patentably new to the entity or person that discovered the new property or mode of operation. I am also informed that there is no requirement that a POSA would have recognized the inherent disclosure at the time of the invention.

41. For anticipation by a prior art publication or document, I understand that the reference's description must enable a POSA to practice the claimed invention without undue experimentation.

D. Subject Matter Eligibility

42. I have been informed and understand that pursuant to 35 U.S.C. § 101, *Mayo Collaborative Servs. v. Prometheus Labs., Inc*., 566 U.S. 6 (2012), *Alice Corp. Pty. V. CLS Bank Int'l*, 573 U.S. 208 (2014), and related case law, patent claims when read individually and as a whole that are directed at laws of nature, natural phenomena, and/or abstract ideas that do not contain elements sufficient to ensure that the patent in practice amounts to significantly more than a patent upon an ineligible concept, are not eligible for patent protection and are invalid.

43. I have also been informed that the question of whether a claimed invention is directed to patent eligible subject matter is addressed by a two-step test: (1) are the patent claims directed to a patent-ineligible concept (e.g., laws of nature, natural phenomena, and/or abstract ideas); and (2) whether the claim

elements, considered individually and as a combination, transform the nature of the claims into patent-eligible subject matter. I have further been informed that when considering the second step, patent claims that simply recite conventional steps are insufficient to provide an inventive concept to transform the claims into patent-eligible subject matter.

E. Credible Utility

44. I understand that a patent claim is invalid if the specification does not provide any data or other information demonstrating a substantial likelihood that the invention will work as described and claimed.

45. I understand that the enablement requirement incorporates the utility requirement of 35 U.S.C. § 101, which requires that the specification disclose as a matter of fact a practical utility for the invention. I understand that the utility requirement under section 112 must be satisfied in the specification itself and is determined as of the effective filing date of the application. I understand that the utility requirement prevents mere ideas, research proposals, or inventions that are simply an object of research from being patented. I also understand that inventions do not meet the utility requirement if the asserted uses represent merely hypothetical possibilities. I have further been informed that patent applications claiming new methods of treatment are supported by test results. I understand that where there is no indication that one skilled in the art would accept without

question statements as to the effects of the claimed formulations and no evidence was presented to demonstrate that the claimed formulations do have those effects, an applicant has failed to demonstrate sufficient utility and therefore cannot establish enablement.

F. Written Description

46. I understand that a patent claim is invalid if the patent does not contain an adequate written description of the claimed invention. I understand the test for written description is whether the specification would have objectively demonstrated to a POSA that the patent applicant actually invented, or "possessed," the claimed subject matter when the patent application was filed. The written description requirement does not require disclosure of examples or an actual reduction to practice of the claimed invention. However, the specification must show possession of the invention on its face, and evidence of reduction to practice outside of the specification is not sufficient by itself to satisfy the written description requirement.

47. I understand that the touchstone of the written description requirement is that the disclosure within the four corners of the patent at issue is what determines whether the inventors had possession of the invention. Whether possession of the invention is shown in the disclosure is an objective inquiry limited to only what is disclosed within the specification of the patent document. I understand that actual

possession or a reduction to practice outside the specification is not enough. It is the specification that must demonstrate possession.

48. I understand that the written description requirement ensures that the inventor claims only that which she actually invented, and precludes the patentee from extending the claims to cover that which was not described but is instead merely obvious over what was expressly disclosed. It is the specification, not the knowledge of one of ordinary skill in the art, that must demonstrate possession of the invention.

49. I am also informed that the full scope of the claim must be disclosed in the specification. As I understand it, where the claims are broad, the disclosure must be correspondingly broad.

G. Enablement

50. I understand that a patent claim is invalid if the specification does not teach a POSA how to make and use the full scope of the claimed invention without undue experimentation. Enablement is determined from the point of view of a POSA at the time when the patent application was filed. I further understand that the following factors may be considered to determine whether any experimentation would have been undue:

- The quantity of experimentation necessary.
- The amount of direction or guidance presented.

- The presence or absence of working examples.
- The nature of the claimed invention.
- The state of the prior art.
- The relative skill of those in the art.
- The predictability or unpredictability of the art.
- The breadth of the claims.

IV. SUMMARY OF OPINIONS

51. For purposes of this report, I have been asked to provide my analysis and opinions concerning the invalidity of asserted claims 1, 2, 6 and 7 of the ’802 Patent. I reserve the right to respond to any opinions or evidence offered by experts on behalf of Trutek concerning the invalidity of the claims of the ’802 Patent. Further, I reserve the right to supplement this report to address any claim construction positions raised by Trutek and/or in response to any order issued by the Court on claim construction.

52. The opinions set forth in this report are based on my education, knowledge and experience in the area over the past 29 years.

53. In my opinion, claims 1, 2, 6 and 7 of the ’802 Patent are invalid as anticipated and/or are obvious in view of the prior art described herein under 35 U.S.C. §§ 102 and 103.

54. It is also my opinion that claims 1, 2, 6 and 7 of the ’802 Patent are not directed to patent-eligible subject matter under 35 U.S.C. § 101.

55. Finally, it is also my opinion that claims 1, 2, 6 and 7 of the ’802 Patent do not satisfy utility, written description and enablement requirements of 35 U.S.C. § 112.

V. OVERVIEW OF THE ’802 PATENT

56. The ’802 Patent is titled “Electrostatically Charged Multi-acting Nasal Application, Product, and Method.” The named inventor is Ashok Wahi. The named assignee of the ’802 Patent is Trutek Corp. (“Trutek”).

57. The ’802 Patent issued on April 24, 2012, from U.S. Application No. 12/467,271 (the “’271 Application”) filed on May 16, 2009. (Ex. 1, Cover.) The ’802 Patent claims priority to Provisional Application No. 61/078,478, filed on July 7, 2008. (Ex. 1, Cover.)

58. The ‘802 Patent recognizes that “[a]irborne microorganisms are a major cause of respiratory ailments in humans, causing allergies, asthma, and pathogenic infections of the respiratory tract.” (Ex. 1 at 3:61-63.)

59. The ‘802 Patent states that it involves “the ***use of products heretofore developed*** for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages.” (*Id.* at 1:62-67.) The ‘802 Patent explains that earlier Wahi patents, including Wahi ’488

and Wahi '481, "describe electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled." (*Id.* at 2:42-45.) The '802 Patent asserts that "those compositions simply create an electrostatic field that helps to filter out oppositely charged materials" and thus "suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream." (*Id.* at 2:45- 52.) The '802 Patent purports to provide a composition that will also "inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition" and thus "prevent[] or of substantially reduc[e] the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents." (*Id.* at 3:4-23.) But as detailed below, it is my opinion that the prior art ***did*** disclose this solution as well.

60. The '802 Patent explains that the claimed composition is "applied to the exterior region around the nostril and/or slightly inside the edge of the nostril" and "creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto." (*Id.* at 2:43-45, 2:62-65, 3:36-39.) But the '802 Patent claims that the composition is formulated such that "contaminants including viruses,

bacteria, and other harmful microorganisms or toxic particulates" are "inactivate[d] dermally outside the body and render[ed] harmless." (*Id.* at 2:2-7.)

61. The '802 Patent discloses the use of various quaternary ammonium salts (aka quaternary ammonium compounds or "QACs"), including Polyquaternium-10 (aka Celquat 400) and benzalkoniun chloride ("BAC"). (*Id.* at 5:14-19, claims 4, 6-7, 10.) It further discloses the use of BAC as both the cationic and biocidic agent. (*Id.* at Tables 7 and 9, 3:33-40.)

62. I understand that the original independent claims 1, 2, and 8 recited a method or formulation for "electrostatically ***preventing*** harmful particulate matter from infecting an individual." (Ex. 3 at 35 (emphasis added).) I understand that, on August 25, 2011, the examiner issued a Non-final Rejection under 35 U.S.C. § 112, first paragraph, stating that the "specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same." (*Id.* at 53.) The examiner explained that the word "***inhibiting***" allows "at least one infectious material to pass into the system of the host," while the word "***preventing***" "indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host." (*Id.* at 54.)

63. I understand that, on February 22, 2012, the Patent Owner amended the independent claims to change the word "preventing" to "inhibiting." (*Id.* at 71.) The examiner issued a Notice of Allowance on March 12, 2012. (*Id.* at 82.) The '802

Patent issued on April 24, 2012. (Ex. 1 at Cover.) I understand that no prior art was cited or characterized by the Examiner during the prosecution of the '802 Patent in any Office Action. (Ex. 3.)

64. Asserted claims 1, 2, 6 and 7 of the '802 Patent are listed below:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.
>
> 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivates the particulate matter and renders said particulate matter harmless.

6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

VI. THE PERSON OF ORDINARY SKILL IN THE ART

65. The '802 Patent issued from U.S. App. No. 12/467,271 (the "'271 application"), which in turn was filed on May 16, 2009. (Ex. 1 at Cover.) The patent claims priority to provisional application No. 61/078,478, which was filed on July 7, 2008. (*Id.*) For purposes of this Opening Report only, I assume that the '802 Patent is entitled to the July 7, 2008 priority date.

66. I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the alleged invention, the sophistication of the technology, the type of problems encountered in the art, and the prior art solutions to those problems.

67. In determining the characteristics of a hypothetical person of ordinary skill in the art of the '802 Patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the '802 Patent. Finally, I placed myself back in the

relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

68. It is my opinion that the art of the subject matter of the ’802 Patent is a pharmaceutical formulation. Based on the materials I have considered, my own experience, and the knowledge required to design pharmaceutical formulation including the use of excipients, I came to the conclusion that the characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team— including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

VII. OVERVIEW OF THE TECHNOLOGY

69. I discuss in the following section the knowledge that skilled artisans would bring to bear in reading the prior art.

A. Biocides and Cationic Agents

70. Biocides encompass a broad range in antimicrobial activity ranging from inhibiting growth (known as “static”) to killing (known as “cidal”). (Ex. 18

at 9.) Biocides have three general uses: (1) sterilization, (2) disinfection, and (3) preservation. (Ex. 19 at 307.) The same chemical agent can be used for all three purposes, depending on the concentration at which it is employed. (*Id.* at 307-308.) Sterilization describes a process that destroys or eliminates all forms of microbial life. (Ex. 18 at 8.) Disinfection describes a process that eliminates many or all pathogenic microorganisms, except bacterial spores, on inanimate objects. (*Id.*) Preservation describes the process of preventing biologic deterioration of materials by, for example, preventing microorganisms from growing in a solution. (Ex. 20 at 22.) Preservation does not involve killing micro-organisms.

71. As early as 1915, QACs were known to have cationic and biocidic properties. (Ex. 20 at 225.) Cationic agents are by definition positively charged when in contact with moisture or in aqueous solution. QACs maintain a permanent positive charge in both acid and alkaline aqueous environments. (*Id.* at 242.) They are useful for both disinfection and preservation. (*Id.* at 247-248, 250.)

72. The antimicrobial mechanism of QACs was well known by the 1930s. Bacteria are unicellular microorganisms composed essentially of cell wall, cytoplasmic membrane, and cytoplasm. (Ex. 21 at 752.) Bacterial cell surfaces are usually negatively charged. (*Id.* at 755.) Cationic QACs are attracted to negatively-charged bacterial cell surfaces. (Ex. 20 at 250-251.) QACs kill bacteria through the following processes: (1) adsorption onto the bacterial cell surface; (2)

diffusion through the cell wall; (3) binding to the cytoplasmic membrane; (4) disruption of the cytoplasmic membrane; (5) release of cytoplasmic elements such as phosphate ions and DNA; and (6) death of the cell. (Ex. 21 at 755; Ex. 22 at 290.) The mechanism is similar for other microorganisms. (Ex. 20 at 251-252.)

73. Use of QACs as disinfectants started early in the 1930s. (Ex. 21 at 744.) For example, QACs were applied as a protective coating on metal, wood, rubber, and plastic (Ex. 7), and as an additional layer of protection on personal protective equipment such as gloves, face masks, and cover gowns (Ex. 33).

74. Celquat SC 240 C (aka Polyquaternium-10) is a polymeric QAC and quaternary thickener. (Ex. 23 at 69.) Celquat SC 240 C is used in cosmetics as a disinfectant at concentrations of up to 5%. (Ex. 17 at 335.)

B. Benzalkonium Chloride (BAC)

75. BAC is another well-known class of QACs. (Ex. 20 at 226; Ex. 31 at 61.) BAC has been used as both a preservative and a disinfectant in pharmaceuticals for decades. (Ex. 20 at 226.) For preservation in pharmaceuticals, BAC is used at concentrations of 0.01% to 0.02%. (Ex. 17 at 589, 602.) For topical disinfection purposes, BAC is used at concentrations of up to 0.1% on the skin—the threshold for human skin sensitivity. (*Id.* at 589, 592.) For non-topical applications, such as

shampoos, rinses, tonics, conditioners etc., the concentration can be as high as 5%. (*Id.* at 589, 592.)

76. BAC has also been used as a preservative in nasal formulations since at least the 1970s. (Ex. 24 at 379-380; Ex. 31 at 61.)

C. Preventing Inhalation of Airborne Contaminants

77. Airborne microorganisms are a major cause of respiratory irritation and infection in humans. The human nose has natural mechanisms for preventing the inhalation of contaminants and inhibiting infections. (Ex. 26 at 8; Ex. 27 at 1, 495-498.) For example, the vibrissae in the nasal vestibule form a mechanical barrier that filters inhaled air by trapping larger particles. (Ex. 29 at 188; Ex. 26 at 10.) The nasal mucus and respiratory epithelium form mechanical and chemical barriers. (Ex. 29 at 188); see also Ex. 28 at 224.) Nasal secretions contain constituents with immunological properties that can neutralize contaminants in the nose. (Ex. 26 at 8.)

78. But it has long been recognized that there is a need to supplement the nose's natural mechanisms for preventing infection. Thus, various mechanisms for preventing the inhalation of harmful or infectious agents using electrostatic forces were developed. For example, it was known since the 1980s that dust filters "made of electret fibers have high dust removing performances and are therefore suitable for attaining a high degree of cleanliness." (Ex. 1034 at 1:22-25.) As detailed below,

Wahi had publicly disclosed nasal products that use an electrostatic charge created by QACs to prevent contaminants from entering the nose at least as early as 1995. Further, it was recognized at least as early as 2006 that iodine (a known QAC) could enhance mechanical filters. (Ex. 30 at ii.) Similarly, facemasks coated in QACs (Ex. 1 at 2:28-30; see also Ex. 1036 at [0044]) and nasal filters with positively ionized filtering components (Ex. 1037 at Abstract) were also known to filter out airborne contaminants.

D. Films Applied to the Skin and Mucosal Surfaces

79. When gels, emulsions, ointments, creams, pastes, and aerosols are applied to the skin, they leave a film once any excess liquid in them evaporates. The cationic properties of formulations that use BAC or other QACs promote strong binding to nasal tissue, thereby increasing the viscoelastic nature of formulations. (Ex. 25 at 39.) Thus, the viscosity of a formulation affects its adhesion to the skin and its internal cohesion and thickness. (Ex. 16 at 481-482.) Viscosity is a measure of a substance's resistance to flow: low viscosity means that the intermolecular forces are weaker, and the fluid is less resistant to movement, while high viscosity means that the intermolecular forces are greater, and the fluid is more resistant to movement. (Ex. 16 at 481-482.) Increased viscosity and cohesion can be achieved by the addition of soluble polymer mixtures and/or bioadhesive materials. (*Id.* at 640.)

80. Film thickness over a specific surface area is dictated by the concentrations of film-forming excipients, viscosity, and the volume or mass of the formulation. (Ex. 16 at 640.) Thick, viscous liquids better adhere to the surface to which they are applied. (Ex. 22 at 109.)

VIII. OVERVIEW OF THE PRIMARY PRIOR ART REFERENCES

81. Before providing a detailed analysis of how the prior art invalidates the Challenged Claims, I provide a brief summary of the key prior art references.

A. Overview of Wadstrom

82. Wadstrom recognizes "[a]n increasing problem of airborne microbes and viruses (e.g. Influenza and SARS) and microbial antigens in airborne infections and associated diseases such as asthma." (Ex. 3 at [1002].) Wadstrom discloses "products, e.g. barriers/filters, to trap airborne . . . bacteria, viruses and fungi . . . for protecting patients, hospital personnel and people in general during epidemics." (Ex. 3 at [0003].) The disclosed product "includes a first support matrix connected to a hydrophobic entity and a second support matrix connected to a positively charged entity." (*Id.* at Abstract.)

83. The support matrix may "be present in particulate form allowing the application of the product . . . by means of a nasal spray or an ointment." (Ex. 3 at [0007].) Thus, Wadstrom discloses, among other embodiments, "a nasal spray . . . for capturing . . . airborne . . . microorganisms, as well as . . . airborne . . . viruses

in the nasal cavity" as well as "an ointment" for capturing the same types of contaminants "on the skin of . . . humans." (*Id.* at [0006].) Wadstrom further discloses that the first support matrix can comprise "cellulose" such that the product forms a "hydrogel." (*Id.* at [0010], [0012].)

84. "[T]he positively charged entity" associated with the second support matrix can comprise a "quaternary ammonium group." (*Id.* at [0009].) Wadstrom observes that "all microbes and viruses are negatively charged" such that this "principle may be used to trap airborne and/or liquid borne allergens." (*Id.* at [0004], [0020].) Thus, Wadstrom's proposed solution is to use products with a positively charged entity that "binds, preferably airborne . . . microorganisms such as bacteria as well as viruses." (*Id.* at [0001].) Wadstrom also discloses that its claimed formula "efficiently bound" at least two different types of bacteria (i.e., Escherichia coli and Staphylococcus aureus). (*Id.* at [0031].)

B. Overview of Rolf

85. Rolf is directed to preventing infection caused by harmful particulate matter, such as "airborne pathogens, respiratory tract pathogens, or a combination thereof." (Ex. 4 at [0019]; *Id.* at [0021].)

86. To achieve this goal, Rolf discloses a device consisting of an "ointment or gel on a backing" that can be applied "in the vicinity of the nasal passageway."

(*Id.* at [0018], [0021], [0042].) Rolf Figure 9 below depicts the use of an embodiment of the claimed device (colored in yellow).

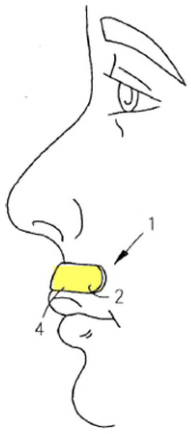


FIG. 9

87. Rolf describes that the device includes a backing, which "is a self-supporting sheet of water soluble or water insoluble, polymeric or natural material that provides strength and integrity for the formulation." (Ex. 4 at [0027], [0047].) The backing has "a front side 3 (the side exposed to the skin during use) and a back side 4 (the side exposed to the environment during use)." (Ex. 4 at [0047].) The backing can be as thin as 0.001 mm. (*Id.* at [0047].) Rolf notes that a formulation is positioned "on," "in" (embedded in whole), or "on and in" (embedded in part) at least a portion of the backing. (*Id.* at [0026], [0042], [0058].)

88. The formulation can "include a pressure sensitive adhesive 14." (*Id.* at [0107].) Rolf explains that the pressure sensitive adhesive is "a unique adhesive vehicle" that enables the device to be "placed upon the skin of a patient (e.g., human)" and stay in "continuous contact with the skin surface of the patient." (*Id.*

at [0041], [0116].) The amount of pressure sensitive adhesive can be adjusted to effectively provide the "requisite adhesiveness." (*Id.* at [0109]; *Id.* at [0110] (listing exemplary range of adhesion adjustment based on a specific adhesive material).)

89. Rolf discloses that the formulation further contains a "prophylactically effective amount of an essential oil, such that the live respiratory virus is inactivated upon contact with the essential oil." (*Id.* at [0178].) The essential oil "effectively kills or inactivates an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (*Id.* at [0071].) The formulation may also comprise an antimicrobial agent, such as benzalkonium chloride (*Id.* at [0252]) and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]).

90. I note that there is no comma between "chloromethyl-methylisothiazolinone" and "benzalkonium chloride" in Rolf's specification at [0252]. But "chloromethyl-methylisothiazolinone benzalkonium chloride" is not an existing compound. I have searched the National Center for Biotechnology Information's PubChem Compound Database, and was unable to locate chloromethyl-methylisothiazolinone benzalkonium chloride. (Ex. 1012.) Each of "chloromethyl-methylisothiazolinone" and "benzalkonium chloride," on the other hand, are well known compounds. (Ex. 1013; Ex. 1014.)

C. Overview of Wahi '488

91. Wahi '488 is primarily "directed to the prevention of harmful effects caused by airborne contaminants which enter the human nasal passage during breathing." (Ex. 6 at 2:62-64.) Such contaminants include "[m]icro-organisms: viruses, germs, bacteria and fungi." (*Id.* at 3:3-4.) The harmful effects of these contaminants can include "discomforts, allergies and diseases." (*Id.* at 3:4-10.)

92. According to Wahi '488, the prior art lacked a "means for protecting the human from harmful affects [*sic*] of airborne contaminants in a practical manner rather than treating the affects [*sic*] of such contaminants." (*Id.* at 3:5-7.) As discussed in Section VII above, this assertion is not accurate. In any event, Wahi '488 claims to address this purported deficiency by using an "electrostatic material" that creates an "artificial electrostatic field in an area near a human nasal passage," "restrict[s] the inhalation of airborne contaminants," and "prevent[s] the contaminants in coming in direct contact with the skin." (*Id.* at 3:12-13, 3:21-23, 3:25-28, 3:31-34.) Wahi '488 explains that the electrostatic material carries charges that "may be positive, negative or combination of both positive and negative charges." (*Id.* at 5:63-67.) In one embodiment, "ointment 21 is positively charged and is applied in the nasal passage area directly while ointment 23 is negatively charged and is applied to the nose." (*Id.* at 7:26-29.) As a result, contaminants that are "essentially negatively charged" would be "repelled by ointment 23" and

"attracted to ointment 21." (*Id.* at 7:34-36.) In another embodiment consisting of a "cream or paste product," as a result of the artificial electrostatic field created by the product, "airborne contaminants such as pollen will be attracted to and adhere to the cream or paste." (*Id.* at 7:12-25.) Wahi '488 explains that a sufficient amount of electrostatic material is required in order to effectively restrict the flow of airborne contaminants into nasal passages. (*Id.* at 3:50-57; *Id.* at claim 1.)

93. The electrostatic material "may be solid, foam, semisolid, gel, hydrogel, a solution, an ointment, a cream, a paste or sol." (*Id.* at 6:50-52.) It "may be applied in its particular physical form directly to a nasal passage or in the area of a nasal passage." (*Id.* at 3:44-46.) It may also be applied to a substrate "which could be attached to the face or nasal area." (*Id.* at 3:60-61.)

D. Overview of Wahi '481

94. Like Wahi '488, Wahi '481 "is primarily directed to the prevention of harmful effects caused by airborne contaminants which enter the human nasal passage during breathing." (*Id.* at 2:66-3:1.) Wahi '481 again notes that "the prior art is lacking in means for protecting the human from harmful effects of airborne contaminants in a practical manner rather than treating the affects [*sic*] of such contaminants." (*Id.* at 3:1-5.)

95. Wahi '481 discloses a "product and method for restricting the flow of airborne contaminants into a nasal passage" that "involves creating an electrostatic

field in an area near a nasal passage." (Ex. 7 at Abstract.) "The electrostatic field may either repel or attract airborne contaminants or both." (*Id.*) Wahi '481 explains that "the product may take the form of a plurality of masses of one or more electrostatic materials," where the mass have "sufficient charge to create an electrostatic field which will prevent at least some airborne contaminants from passing into a nasal passage." (*Id.*) "Among the specific electrostatic materials which may be used in the present invention are . . . Quarternary Ammonium Compounds, . . . Fatty or Polymer derived Quarternary Ammonium Compounds, and their equivalents." (*Id.* at 3:58-63.) A person of ordinary skill in the art would understand "Quarternary Ammonium Compounds" to be a misspelling of commonly-known "Quaternary Ammonium Compounds." Wahi '481 provides exemplary formulations that should be used. (*Id.* at Examples 1-4.)

96. Wahi '481 teaches that "there is also a carrier material with the plurality of masses dispersed therein." (*Id.* at Abstract.) "The product may be a topical solution, a semi solid, a solid, a spray solution or a vaporizable solution. Alternatively, it may be in a form which includes a substrate for the carrier and, in one preferred embodiment, the substrate would be an adhesive material such as a bandage." (*Id.*)

97. Wahi '481 Figure 2 "shows a partial side stylized view of a face 1 including a nasal passage 3." (*Id.* at 7:59-60.) The figure shows "an electrostatic field is represented as typical by grid 5." (*Id.* at 7:63-64.)

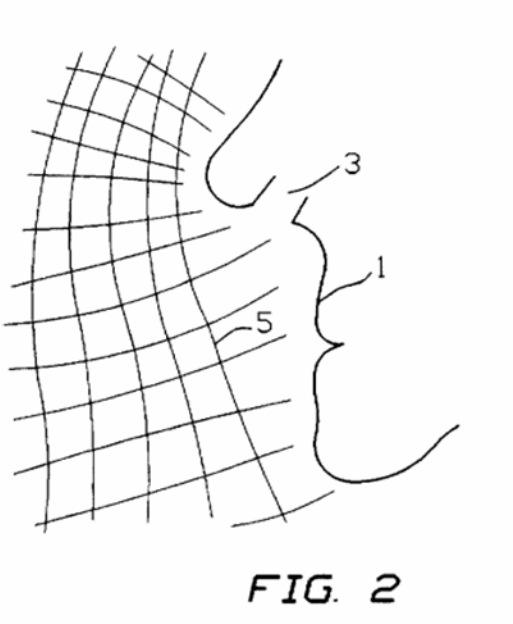


FIG. 2

E. Overview of Baker '189

98. Baker '189 issued on May 6, 2003 discloses: (1) antimicrobial nanoemulsion compositions comprising cationic containing compounds (e.g., cetylpyridinium chloride ("CPC")); (2) the use of quaternary ammonium compounds for broad-spectrum antimicrobial agents (e.g., benzalkonium chloride); (3) nasal and topical forms, including application to the skin or nasal mucosa; (4) topical applications where the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel; and (5) use of CPC as a

cationic agent containing compound and tri-butyl phosphate ("BTCP") as the biocide.

99. Baker '189 discloses "compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses." (Ex. 8 at Abstract.) "In certain other embodiments, the compositions of the present invention further comprise one or more cationic halogen containing compounds." (*Id*. at 3:50-53.)

100. "In preferred embodiments, the cationic halogen-containing compound is preferably premixed with the oil phase; however, it should be understood that the cationic halogen-containing com pound may be provided in combination with the emulsion composition in a distinct formulation. Suitable halogen containing compounds may be Selected, for example, from compounds comprising chloride, fluoride, bromide and iodide ions." (*Id*. at 17:10-18.) "The nanoemulsions Structure of the certain embodiments of the emulsions of the present invention may play a role in their biocidal activity as well as contributing to the non-toxicity of these emulsions." (*Id*. at 22:10-13.) "Ingredients for use in the non-toxic nanoemulsions include, but are not limited to . . . quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (*Id*. at 30:29-30, 38-40.) Moreover, Baker '189 teaches that the non-toxic nanoemulsions "have antimicrobial activity against most vegetative bacteria (including Gram positive

and Gram-negative organisms), fungi, and enveloped and nonenveloped viruses in 15 minutes (e.g., 99.99% killing); and they have sporicidal activity in 1–4 hours (e.g., 99.99% killing) when produced with germination enhancers." (*Id*. at 31:62-67.)

F. Overview of Baker '476

101. Baker '476 filed on October 30, 2007, is a continuation-in-part of the '189 patent and has the same disclosure of the '189 patent in addition to disclosing an embodiment comprising CPC and a benzyl ammonium chloride compound (specifically, alkyldimethyl-3,4-dichlorobenzyl ammonium chloride). (Ex. 8, at [0232].)

G. Overview of Khaled

102. Khaled discloses: (1) antimicrobial thin film coatings comprising a polyelectrolyte complex, wherein the positively charged polyelectrolytes and the negatively charged polyelectrolytes arrange themselves into a polyelectrolyte complex, rather than an alternating multi-layer structure; (2) the disclosed films can further include a biocide (Ex. 9, at [0053] ("The biocide functional groups bonded chemically or physically in the polymer structure, as an auxiliary biocide to the thin film, may include … quaternary ammonia compounds").)

H. Overview of Rabe

103. Rabe discloses "stabilized electrostatically-sprayable topical compositions" comprising a liquid insulating material (e.g., volatile silicones, volatile hydrocarbons), one or more conductive materials (e.g., C8-C20 isoparaffin, water, alcohols, glycols, polyols and ketones, etc.), a particulate materials and thickeners (e.g., wax or clays). (Ex. 12, at Abstract; 4:12-5:13; 5:14-55; 7:21-30.)

104. Sprays can include quatemium/benzalkonium compounds (e.g., Quaternium-18/Benzalkonium Bentonite. (*Id*., at 8:20-44), Various further anti-microbial agents can also be included. (*Id*. at 9:11-13.)

I. Overview of Katz

105. Katz discloses multiple nasal sprays including BAC. (*See* Ex. 13, at [0078]-[0081]). For example, paragraph [0079] provides that "1.5 fl. oz. (45 ml) of Afrin® moisturizing saline mist solution may be purchased commercially over the counter (Schering-Plough, Memphis, Tenn.). The solution contains water, PEG-32, sodium chloride, PVP, disodium phosphate, sodium phosphate, benzalkonium chloride, and disodium EDTA." (Ex 13, at [0079].)

J. Overview of Wahi '790

106. Wahi '790 discloses: (1) a "nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by

creation of a proximate, enhanced electrostatic field"; and (2) compositions comprising one or more electrostatic polymers (e.g., poly(dimethyl diallyl ammonium chloride)polymer) and a topical carrier (e.g., a diluent such as alcohol, glycerins, organic surfactant, natural oil, etc.). (Ex. 14, at Abstract; [0024], [0032], claims 1, 4, and 6.)

107. Wahi '790 discloses "a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field." (*Id*. at Abstract.)

ANTICIPATION AND OBVIOUSNESS

IX. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF WADSTROM ALONE, OR IN COMBINATION WITH ROLF

A. Independent Claim 1[1]

(a) A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

108. Whatever the scope of the term "inhibiting harmful particulate matter from infecting an individual through nasal inhalation," in my opinion, Wadstrom alone or in view of Rolf discloses this limitation because it discloses preventing all particulate matter from infecting an individual.

[1] I understand an "independent" claim to be a claim that does not reference any other claims in the patent.

109. In particular, Wadstrom discloses "a nasal spray . . . for capturing . . . airborne . . . microorganisms, as well as . . . airborne . . . viruses in the nasal cavity." (Ex. 3 at [0006].) Wadstrom observes that, because "all microbes and viruses are negatively charged," this "principle may be used to trap airborne and/or liquid borne allergens." (*Id.* at [0004], [0020].) The disclosed products include a "support matrix connected to a positively charged entity." (*Id.* at Abstract.) Thus, it is my opinion that the positively charged product is used to electrostatically attract negatively charged contaminants before they enter the nasal passage. Wadstrom discloses that its claimed formula "efficiently bound" at least two different types of bacteria. (Ex. 3 at [0031].) In my opinion, a person of ordinary skill in the art would understand that if contaminants are bound outside the nasal cavity, they will not be inhaled or cause infection. Thus, Wadstrom discloses products that electrostatically prevent infection through nasal inhalation.

110. In addition and separately, Wadstrom combined with Rolf discloses this element. Rolf discloses a "method for ***preventing*** a respiratory infection" that comprises use of a product "located in the vicinity of the nasal passageway." (Ex. 4 at Claim 1; *see also id.* at Abstract, [0019], [0020], [0021].) In my opinion, a person of ordinary skill in the art would understand the word "preventing" indicates that not even one of the infectious materials is allowed to infect the host. Thus,

Rolf discloses preventing all particulate matter from infecting an individual through nasal inhalation.

111. I am further of the opinion that a person of ordinary skill in the art would have been motivated to combine Rolf with Wadstrom to arrive at the claimed invention. ***First,*** Wadstrom and Rolf describe complementary methods for preventing nasal inhalation of airborne contaminants that cause infection. Wadstrom discloses a product that addresses the problem of "infections and associated diseases" by "absorb[ing]" and "trap[ping]" airborne contaminants using a "positively charged entity" that is applied via "ointment" or "nasal spray" to the skin around the "nasal cavity." (Ex. 3 at [0001], [0002], [0004], [0006], [0009], [0020].) Rolf similarly discloses a "method for preventing a respiratory infection" using a formulation that is applied "in the vicinity of the nasal passageway," wherein the formula "kills or inactivates" airborne pathogens. (Ex. 4 at Claim 1, [0252], [0071].) In my opinion, a person of ordinary skill in the art would have recognized the benefit of combining the contaminant killing features of Rolf with the contaminant attracting and trapping features of Wadstrom as doing so would further Wadstrom's goal of preventing pathogens from entering the nasal tract and causing infection.

112. ***Second,*** the teaching of quaternary ammonium compounds in Wadstrom would have led a person of ordinary skill in the art to employ the

teachings of Rolf relating to the use of benzalkonium chloride. In particular, Wadstrom discloses using a "positively charged entity" comprised of a "quaternary ammonium group." (Ex. 3 at [0001], [0002], [0006], [0009].) Rolf discloses supplementing its primary mode of action (i.e., essential oils) with BAC—a known QAC—as antimicrobial agents to further the goal of preventing pathogens from causing infection. (Ex. 4 at [0153], [0252]; Section VII.A.) A sufficient concentration of BAC could act as an antimicrobial agent as disclosed in Rolf. (Ex. 17 at 589, 592; Ex. 19 at 307-308.) Up to 0.1% of BAC could be applied to the skin, such a concentration would have biocidic effects. (Section VII.B; Ex. 17 at 589, 592.) Thus, in my opinion, a person of ordinary skill in the art would recognize that QACs as disclosed in Wadstrom—and in particular BAC, as discussed in Rolf—could be used not only to absorb contaminants but also to kill contaminants, furthering the disclosed purpose of Wadstrom of addressing infections. (Section VIII.A.) Accordingly a person of ordinary skill in the art would have had a reasonable expectation of success in combining Wadstrom and Rolf, as the two systems are complementary and compatible. Thus, Wadstrom alone or in view of Rolf discloses a method for electrostatically inhibiting all harmful particulate matter from infecting an individual through nasal inhalation.

(b) a formulation is applied to skin or tissue of nasal passages of the individual in a thin film

113. Wadstrom discloses a formulation that is applied to the skin or tissue of the nasal passages. For example, Wadstrom discloses, among other embodiments, "a nasal spray . . . for capturing . . . airborne . . . microorganisms, as well as . . . airborne . . . viruses in the nasal cavity." (Ex. 3 at [0006].) Wadstrom further discloses "an ointment" for capturing the same types of contaminants "on the skin of . . . humans" as well as a "hydrogel." (*Id.* at [0006], [0007], [0010], [0012].) In my opinion, a person of ordinary skill in the art would understand that an ointment or hydrogel can also be applied to the skin inside or around the nasal passage, and would have been motivated to do so given the purpose of Wadstrom of addressing the "increasing problem of airborne microbes and viruses" that can be inhaled through the nose. (*Id.* at [0001], [0002].) I am further of the opinion that a person of ordinary skill in the art would further understand that, when sprays, ointments, or hydrogels are applied to the skin, they form a thin film once excess liquid evaporates. (*See also* Section VII.D.)

114. In addition and separately, Wadstrom in view of Rolf renders obvious this claim element. Rolf discloses a device that is an "ointment or gel on a backing" and that the formulation can be "embedded" into the backing. (Ex. 4 at [0042], [0026], [0058].) The backing of the patch can "include[] . . . films." (*Id.* at [0198].) The backing can be "about 0.001 mm to about 5.0 mm, about 0.001 mm to about 3.0 mm, or about 0.025 mm to about 1.25 mm." (*Id.* at [0027], [0047].) In

my opinion, a person of ordinary skill in the art would understand a film with a 0.001 mm thickness to be a thin film. I am further of the opinion that a person of ordinary skill in the art would have been motivated to combine the teachings of Wadstrom with the teachings of Rolf (Section IX.A.a), and would have understood that making the film disclosed in Wadstrom as thin as about 0.001 mm would be more comfortable for a person to wear around their nasal passages than a thick film. Thus, Wadstrom alone, or in combination with Rolf, discloses a formulation that is applied to the skin or tissue of nasal passages of the individual in a thin film.

(c) electrostatically attracting the particulate matter to the thin film

115. Wadstrom discloses products that use a positive electrostatic charge to attract negatively charged contaminants. Wadstrom discloses a product that uses a positively charged product to attract negatively charged contaminants, and thereby achieves the purpose of "absorption of airborne and/or liquid borne microbes as well as viruses, and microbial antigens including allergens." (Ex. 3 at [0001], [0031]; Section IX.A.a.) Wadstrom thus discloses electrostatically attracting the particulate matter to the thin film.

(d) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

116. Wadstrom discloses binding contaminants to the thin film. In particular, Wadstrom discloses a "product for . . .absorption of airborne . . . microbes as well as viruses, and microbial antigens" that "binds" the contaminants using a "positively charged entity," which attracts negatively charged contaminants to the product. (*Id.* at [0001], [0004], [0020].)

117. Wadstrom further discloses adjusting the adhesion of the thin film so that the thin film sticks to the skin or tissue, as well as adjusting the cohesion of the thin film so that it is impermeable. In particular, Wadstrom discloses a "support matrix," which can consist of cellulose and may form a "hydrogel." (*Id.* at [0001], [0012].) Wadstrom discloses that the support matrix may consist of "a nasal spray" or "an ointment" for capturing contaminants "on the skin of . . . humans" and that "other components for use in ointments," which are "known for a person skilled in the art," may be used. (*Id.* at [0006].) Wadstrom further discloses that the product can be a "hydrogel." (*Id.* at [0010], [0012].) In my opinion, a person of ordinary skill in the art would understand that a nasal spray, ointment, hydrogel that is applied to the skin is intended to stick to the skin or tissue and would adjust the viscosity (and thereby the adhesion) of the formulation in order to achieve that intended purpose. (Section VII.D.) I am also of the opinion that because the contaminants are absorbed and bound by the support matrix and the support matrix sticks to the skin, the contaminants are held in place.

118. Given that the disclosed purpose of Wadstrom is "absorption of airborne . . . microbes as well as viruses, and microbial antigens" in order to "remove these agents and antigens" and address the "increasing problem of airborne microbes and viruses," (Ex. 3 at [0001], [0002]), in my opinion, a person of ordinary skill in the art would adjust the viscosity (and thereby the impermeability) of the formulation in order to achieve the intended purpose of preventing any contaminants from contacting the skin.

119. In addition and separately, Wadstrom combined with Rolf discloses this limitation. In particular, Rolf discloses that a formulation that includes a "pressure sensitive adhesive 14" that enables the device to be "placed upon the skin of a patient" and stay in "continuous contact with the skin surface." (Ex. 3 at [0107], [0041], [0116].) The amount of pressure sensitive adhesive can be adjusted to effectively provide the "requisite adhesiveness." (*Id.* at [0109]; *id.* at [0110] (listing exemplary range of adhesion adjustment based on a specific adhesive material).)

120. Rolf further discloses adjusting cohesion to provide adequate impermeability to the thin film. Rolf discloses "an ointment or gel on a backing" wherein "use of a backing material that has been treated with a sizing agent allows for the effective control of the rate of penetration, such that the gel or ointment has solidified after it has begun to penetrate the backing, but before it has passed

completely through the backing." (Ex. 4 at [0042], [0052].) Rolf further discloses that "the use of a backing material that has been treated with a sizing agent allows for the effective control of the depth to which the ointment or gel will easily penetrate before solidifying." (*Id.* at [0052].) Rolf further discloses that the backing can be "non-porous." (*Id.* at [0192].) In my opinion, a person of ordinary skill in the art would understand that a backing that is non-porous and/or cannot be penetrated is impermeable. I am also of the opinion that a person of ordinary skill in the art would further understand that increasing the amount of sizing agent would increase impermeability. A person of ordinary skill in the art would have been motivated to combine the impermeability feature taught by Rolf with the electrostatic formula taught by Wadstrom to ensure that any contaminants captured by the formula do not come in direct contact with the skin thereby perpetuating the "increasing problem of airborne microbes and viruses" that Wadstrom is intended to address. (Ex. 3 at [0001], [0002]; *see also* Section IX.A.a.) Thus, Wadstrom alone or in view of Rolf discloses holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.

(e) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless

121. Whatever the scope of the terms "inactivating the particulate matter" and "rendering harmless," in my opinion, Wadstrom alone or in view of Rolf discloses this limitation because it discloses killing target organisms (i.e. disinfection rather than just preservation).

122. The disclosed purpose of Wadstrom is "absorption of airborne . . . microbes as well as viruses, and microbial antigens" in order to "remove these agents and antigens" and address the "increasing problem of airborne microbes and viruses." (Ex. 3 at [0001], [0002].) Wadstrom further discloses using members of a "quaternary ammonium group" to create the requisite positive charge. (*Id.* at [0009].) Sufficient quantities of QACs have not only cationic properties but also can kill contaminants. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.) In my opinion, a person of ordinary skill in the art would be motivated to use a sufficient concentration of QACs to kill contaminants given the purpose of Wadstrom of addressing "airborne infections." (Ex. 3 at [0001], [0002].) A person of ordinary skill in the art would understand that Wadstrom would more effectively achieve its intended purpose if contaminants bound outside the nose were killed so that they do not concentrate outside the nose and/or inadvertently get wiped into the nose in an active state.

123. In addition and separately, Wadstrom combined with Rolf discloses this element. Rolf discloses a formulation containing an ingredient that

"effectively ***kill[s] or inactivate[s]*** an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0071] (emphasis added).) Rolf discloses that that ingredient can be an essential oil (*id.* at [0021]), an antimicrobial agent, such as BAC (*id.* at [0252]), and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*Id.* at [0154].) In my opinion, a person of ordinary skill in the art would have been motivated to combine Wadstrom and Rolf and would have had a reasonable expectation of success in doing so. (Section IX.A.a.) Thus, Wadstrom alone or in view of Rolf discloses inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

B. Independent Claim 2

124. Claim 2 recites "[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film; b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the

formulation to provide adequate impermeability to the thin film; and c) inactivates the particulate matter and renders said particulate matter harmless." Claim 2 is thus identical to claim 1 except that it claims a formulation rather than a method and includes the following additional limitation: "said formulation comprising at least one cationic agent and at least one biocidic agent." Wadstrom alone or in view of Rolf renders claim 1 obvious. (Section X.A.)

125. Wadstrom further discloses a formulation comprising at least one cationic agent and at least one biocidic agent. In particular, Wadstrom discloses a "support matrix connected to a positively charged entity" that can comprise a "quaternary ammonium group." (Ex. 3 at Abstract, [0009].) A QAC can have biocidic effects if used in the appropriate concentration. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.) Thus, Wadstrom discloses the formulation of claim 1 comprising at least one cationic agent and at least one biocidic agent.

126. In addition and separately, Wadstrom combined with Rolf discloses this element. Rolf discloses a formulation containing an ingredient that "effectively ***kill[s] or inactivate[s]*** an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0071] (emphasis added).) Rolf discloses that that ingredient can be an essential oil (*id.* at [0021]), an antimicrobial agent, such as BAC (*id.* at [0252]), and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf further requires that the ingredient be present

in an "appropriate and suitable amount" to realize this effect. (*Id.* at [0154].) In my opinion, a person of ordinary skill in the art would have been motivated to combine Wadstrom and Rolf and would have had a reasonable expectation of success in doing so. (Section IX.A.a.)

C. Dependent Claim 6[2]

127. Claim 6 recites "[t]he formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride." Wadstrom, alone or in view of Rolf, renders claim 2 obvious. (Section X.B.)

128. Wadstrom further discloses addressing "infection" by absorbing "airborne . . . microbes as well as viruses, and microbial antigens" using a "positively charged entity" comprised of a "quaternary ammonium group." (Ex. 3 at [0001],[2] [0002], [0006], [0009].) BAC is a member of the "quaternary ammonium group." (Ex. 31 at 61.) A sufficient BAC concentration could be used to attract contaminants, furthering the disclosed purpose of Wadstrom of preventing infections. (Section VII.A.)

129. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]). Rolf further requires that the

[2] I understand that a "dependent" claim refers back to a prior claim and incorporates all of the limitations of the claim from which it depends.

ingredient be present in an "appropriate and suitable amount" to realize this effect. (*See, e.g., id.* at [0154].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine the BAC taught in Rolf with Wadstrom's nasal formula. (Section IX.A.a.) Thus, Wadstrom combined with Rolf discloses the formulation of claim 2 wherein the at least one cationic agent is BAC.

D. Dependent Claim 7

130. Claim 7 recites "[t]he formulation of claim 2 wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL." Wadstrom, alone or in view of Rolf, renders claim 2 obvious. (Section X.B.)

131. Wadstrom further discloses addressing "infection" by absorbing "airborne . . . microbes as well as viruses, and microbial antigens" using a "positively charged entity" comprised of a "quaternary ammonium group." (Ex. 3 at [0001], [0002], [0006], [0009].) BAC is a member of the "quaternary ammonium group." (Ex. 31 at 61.) Sufficient quantities of QACs not only have cationic properties but also can kill contaminants. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.) In my opinion, a person of ordinary skill in the art would be motivated to use a sufficient concentration of QACs to kill contaminants given the purpose of Wadstrom of addressing "airborne infections." (Ex. 3 at [0001], [0002].) A person of ordinary skill in the art would understand that Wadstrom would more effectively

achieve its intended purpose if contaminants bound outside the nose were killed so that they do not concentrate outside the nose and/or inadvertently get wiped into the nose in an active state.

132. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]) and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*See, e.g.*, *id.* at [0154].) I am of the opinion that a person of ordinary skill in the art would understand that when BAC and/or lysine hydrochloride are used in sufficient concentrations to act as antimicrobial and/or antiviral agents, they act as biocidic agents. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.) I am also of the opinion that a person of ordinary skill in the art would have been motivated to combine the BAC taught in Rolf with Wadstrom's nasal formula. (Section IX.A.a.) Thus, Wadstrom combined with Rolf discloses the formulation of claim 2 wherein the at least one biocidic agent is BAC or Lysine HCL.

X. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF Wahi '488 ALONE, OR IN COMBINATION WITH ROLF

A. Independent Claim 1

(a) A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

133. Whatever the scope of the term "inhibiting harmful particulate matter from infecting an individual," in my opinion, Wahi '488 alone or in view of Rolf discloses this limitation because it discloses preventing all particulate matter from infecting an individual.

134. Wahi '488 discloses products that use an electrostatic charge to prevent infection. In particular, Wahi '488 discloses "creating an electrostatic field in an area near a human nasal passage" that "may either repel or attract airborne contaminants or both, to ***prevent*** such contaminants from entering the nasal passage and body of a user." (Ex. 5 at Abstract.) Further, Wahi '488 "is primarily directed to the ***prevention*** of harmful effects caused by airborne contaminants which enter the human nasal passage during breathing." (*Id.* at 2:62-64.) Wahi '488 discloses that the product must have "sufficient charge to create an electrostatic field which will ***prevent at least some*** airborne contaminants from passing into a human nasal passage." (*Id.* at Abstract.) Wahi '488 states that the nasal formulation "consist[s] essentially of a plurality of masses of one or more electrostatic polymers,

… so as to create an artificial electrostatic field to ***reduce the flow of charged airborne contaminants passing into said human nasal passage***…." (*Id.* at Claim 1 (emphasis added).)

135. As disclosed by Wahi '488, the purpose of the electrostatic field is to prevent "harmful effects caused by airborne contaminants which enter the

human nasal passage during breathing." (*Id.* at 2:62-64.) Those contaminants include "viruses, germs, bacteria and fungi." (*Id.* at 3:3-4.) Further, Wahi '488 aims to prevent "discomforts, allergies and ***diseases***" caused by human exposure to harmful contaminants. (*Id.* at 3:4-10 (emphasis added).) A person of ordinary skill in the art would thus have understood that the "harmful effects" comprises infection of an individual.

136. In addition and separately, Wahi '488 in view of Rolf discloses this element. Rolf discloses a "method for ***preventing*** a respiratory infection" that comprises use of a product "located in the vicinity of the nasal passageway." (Ex. 4 at Claim 1; *see also id.* at Abstract, [0019], [0020], [0021].) In my opinion, a person of ordinary skill in the art would understand the word "preventing" indicates that not even one of the infectious materials is allowed to infect the host. Thus, Rolf discloses preventing all particulate matter from infecting an individual through nasal inhalation.

137. In my opinion, a person of ordinary skill in the art would have been motivated to employ the contaminant killing features of Rolf with the electrostatically charge formula disclosed in Wahi '488 in order to kill the harmful particulate matter captured by the electrostatically charged formula and further Wahi '488's stated goal of preventing the inhalation of harmful airborne contaminants that may cause diseases. ***First***, both Wahi '488 and Rolf aim to

achieve the same goal: preventing harmful effects caused by inhaling airborne contaminants. The purpose of the Wahi '488 electrostatic field is discussed above. (Ex. 5 at 2:62-64, 3:3-4.) Similarly, Rolf discloses an "antiviral inhalation patch" that "allows for the prevention of other diseases associated with airborne pathogens, respiratory tract pathogens, or a combination thereof." (Ex. 4 at [0019], [0042].)

138. Wahi '488 and Rolf realize this same purpose by adopting highly similar solutions. Wahi '488 discloses creating "an artificial electrostatic field in an area near a human nasal passage" that "restrict[s] the flow of airborne contaminants into a nasal passage." (Ex. 5 at 1:7-8, 3:11-13.) Rolf similarly discloses applying the device "in the vicinity of the nasal passageway" that "effectively kills or inactivates an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0021], [0071].)

139. ***Second***, Wahi '488 states the motivation to combine its teachings with the preventing infection feature in Rolf, disclosing that "[t]he products of this invention may act as ***primary or secondary treatments in conjunction with other known treatments.*** The electrostatic field product of the subject invention, ***may also be added to existing nasal Topicals to enhance their 'effectiveness' in restricting the inhalation of airborne contaminants***." (Ex. 5 at 3:18-30.) In my opinion, this disclosure would have motivated a person of ordinary skill in the art to combine the

method and formulation disclosed in Wahi '488 with the nasal product disclosed in Rolf to further both products' effectiveness in restricting the inhalation of airborne contaminants. ***Third***, Rolf and Wahi '488 introduce complementary implementations of their products. Rolf teaches that the formulation can include "benzalkonium chloride" as an antimicrobial agent. (Ex. 4 at [0252].) BAC has a positive charge and, when used in a sufficient concentration, can attract and kill contaminants that are negatively charged. (Sections VII.A-B; Ex. 17 at 589, 592; Ex. 19 at 307- 308.) Thus, in my opinion, a person of ordinary skill in the art would have appreciated that combining Rolf's disclosure of BAC with the electrostatic attraction feature as disclosed in Wahi '488 would have achieved the predictable benefits of killing the contaminants that Wahi '488's formulation attracts and traps. Thus, Wahi '488 alone or in view of Rolf discloses a method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation.

(b) a formulation is applied to skin or tissue of nasal passages of the individual in a thin film

140. Wahi '488 discloses a formulation that is applied to the skin or tissue of the nasal passages. In particular, Wahi '488 discloses a formulation that contains "one or more electrostatic materials," among other ingredients such as a carrier and an adhesive. (Ex. 5 at Abstract; *see also, id.* at 6:46-66.) The formulation "is applied at or near the nasal passage by … being placed within the accessible regions

of the ***nasal passages.***" (*Id.* at 6:4-7; *see also, id.* at 1:9-14 (product creates "artificial electrostatic field in an area close to, at, or within the nasal passage"); *see also, id.* at 6:24-32 (formula is spread "above the upper lip, and over the nose").) Wahi '488 further discloses application in a thin film. In particular, Wahi '488 discloses that its product may be "semisolid, gel, hydrogel, a solution, an ointment, a cream, a paste…." (*Id.* at 6:47-54.) The solution may also be "a liquid solution or a dispersion, one for spray application or even vaporization." (*Id.* at 6:47-54.) In my opinion, a person of ordinary skill in the art would understand that a product in any of these forms would form a film when applied to the skin. (Section VII.D.) The ointments "typically contain fluid hydrocarbons having about 16 to about 30 carbon atom" or "semisolid hydrocarbons" that "may have from 30 to 50 carbons." (Ex. 5 at 4:30-36.) I am of the opinion that a person of ordinary skill in the art would understand that ointments with about 16 fluid hydrocarbons form a thin film.

141. In addition and separately, Wahi '488 in view of Rolf renders obvious this claim element. Rolf discloses a device that is an "ointment or gel on a backing" and that the formulation can be "embedded" into the backing. (Ex. 4 at [0042], [0026], [0058].) The backing of the patch can "include[] . . . films." (*Id.* at [0198].) The backing can be "about 0.001 mm to about 5.0 mm, about 0.001 mm to about 3.0 mm, or about 0.025 mm to about 1.25 mm." (*Id.* at [0027], [0047].) In

my opinion, a person of ordinary skill in the art would understand a film with a 0.001 mm thickness to be a thin film. In my opinion, a person of ordinary skill in the art would have been motivated to combine the teachings of Wahi '488 with the teachings of Rolf (*see* Section X.A.a.), and would have understood that making the film disclosed in Wahi '488 as thin as about 0.001 mm would be more comfortable for a person to wear around their nasal passages than a thicker film. Thus Wahi '488, alone or in view of Rolf, discloses a formulation that is applied to the skin or tissue of nasal passages of the individual in a thin film.

(c) electrostatically attracting the particulate matter to the thin film

(a) Wahi '488 discloses products that use a positive electrostatic charge to attract negatively charged contaminants. In particular, Wahi '488 discloses a "product which includes the ability to create an artificial electrostatic field in an area close to, at, or within the nasal passage to either repel or attract airborne contaminants, or both, to prevent such contaminants from entering the nasal passage and body of a user." (Ex. 5 at 1:9-14; *see also id.* at Abstract, Claim 6.) Wahi '488 requires a sufficient amount of electrostatic material in order to effectively restrict the flow of airborne contaminants into nasal passages. (*Id.* at 3:50-57.) For example, in one embodiment, a positively charged ointment 21 is applied directly to the nasal passage area and creates a positive electrostatic grid 15 that attracts negatively charged contaminants. (*Id.* at 7:19-39; Fig. 4.)

Thus, Wahi '488 discloses electrostatically attracting the particulate matter to the thin film.

> (d) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

142. Wahi '488 discloses that its formulation adheres to the skin or tissue.

Wahi '488 states that "the product of the present invention with the electrostatic material for creating the field in the area of nasal passages ***may be with*** or without ***an adhesive***." (Ex. 5 at 6:60-63 (emphasis added); *see, id.* at Figure 1.) Further, Wahi '488 repeatedly discloses that the material stays on the skin or tissue for "a predetermined time or for a predetermined quantity of contaminants to be attracted," and should not be "accidentally removed" from the skin or tissue. (*Id.* at 4:66-5:4, 6:7-11). Wahi '488 also discloses that the airborne contaminants are "attracted to and ***adhere to***" the product." (*Id.* at 7:19-25.) Because the airborne contaminants adhere to the product and the product adheres to the skin, the airborne contaminants are held in place.

143. Wahi '488 further discloses providing adequate impermeability to the thin film, as it makes clear that "the present invention will ***prevent the contaminants in coming in direct contact with the skin***." (Ex. 5 at 3:21-23.) Further, Wahi '488 discloses that the formulation may be in the form of "a semisolid" or "a solid." (*Id.* at Abstract.) In my opinion, a person of ordinary skill

in the art would understand that a semisolid—and particularly a solid—are impermeable. Wahi '488 also discloses adjusting the adhesion and cohesion of the product. Wahi '488 discloses a method that "involves applying a topical application having a plurality of masses of one or more electrostatic materials, and a carrier having the plurality of masses dispersed therein." (Ex. 5 at Abstract.) The "topical application may be in the form of a solution, a semisolid, [or] a solid." (*Id.* at Abstract; *id.* at 6:47-54.) The solution may also be "a liquid solution or a dispersion, one for spray application or even vaporization." (*Id.* at 6:47-54; *see also, id.* at 3:13-18, 4:18-23, Figure 1.) The carrier, which is the "material into which electrostatic material may be dispersed," "may be a single material or a combination of materials and the trace of carrier ***depends upon the physical form of the present invention product desired***." (*Id.* at 4:15-18, 6:55-57.) In particular, "the carrier will depend on whether or not one desires a liquid, a solid or a semisolid, whether the liquid is to be sprayed or applied with an applicator, whether or not the semisolid is to be in paste or cream or ointments or other form; whether or not the solid material is to be flexible or rigid or semi flexible." (*Id.* at 4:18-23.)

144. In my opinion, a person of ordinary skill in the art would have known that adjusting the viscosity of the product would determine (at least in part) its "physical form." (Section VII.D.) I am also of the opinion that a person of ordinary skill in the art also would have known that adjusting the viscosity of the product to

vary its physical form would alter the carrier's adhesion and cohesion. Wahi '488 further discloses including "various waxes and/or oils," "hydrocarbon ointments," "polysiloxanes [that] impart to the wax like or ointment like properties, "polyethylene glycol ointments," and "long chain polyethylene glycol polymers" may be added "depending upon the particular feel and consistency of the product." (Ex. 5 at 4:37-52.) These ingredients are examples of bioadhesive materials and/or polymer mixtures. In my opinion, a person of ordinary skill in the art would have known that these ingredients would increase the viscosity—and thus the adhesion and cohesion—of the product. (Section VII.D.) Thus, Wahi '488 discloses adjusting the product's viscosity—and thus adhesion and cohesion—to acquire the desired physical form.

145. In my opinion, a person of ordinary skill in the art would have been motivated to adjust the viscosity—and thus the adhesion and cohesion—of the formula to achieve Wahi '488's disclosed purposes. First, Wahi '488 is intended to ensure that the electrostatic material stays on the skin or tissue and is not "accidentally removed" (Ex. 5 at 4:66-5:4, 6:7-11) and that airborne contaminants "adhere to" the product (*Id.* at 7:19-25). A person of ordinary skill in the art thus would have been motivated to adjust the adhesion of the formula to ensure that it adheres to the skin and that any contaminants adhere to the formula. Second, Wahi '488 is intended to "prevent the contaminants in coming in direct contact with the

skin." (Ex. 5 at 3:21-23.) In my opinion, a person of ordinary skill in the art thus would have been motivated to adjust the cohesion of the formula to ensure that it is sufficiently impermeable that any contaminants do not come in direct contact with the skin. Further, Rolf discloses adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film. In particular, Rolf discloses that a formulation that includes a "pressure sensitive adhesive 14" that enables the device to be "placed upon the skin of a patient" and stay in "continuous contact with the skin surface." (Ex. 3 at [0107], [0041], [0116].) The amount of pressure sensitive adhesive can be adjusted to effectively provide the "requisite adhesiveness." (*Id.* at [0109]; *id.* at [0110] (listing exemplary range of adhesion adjustment based on a specific adhesive material).)

146. Rolf further discloses adjusting cohesion to provide adequate impermeability to the thin film. Rolf discloses "an ointment or gel on a backing" wherein "use of a backing material that has been treated with a sizing agent allows for the effective control of the rate of penetration, such that the gel or ointment has solidified after it has begun to penetrate the backing, but before it has passed completely through the backing." (Ex. 4 at [0041], [0052].) Rolf further discloses that "the use of a backing material that has been treated with a sizing agent allows for the effective control of the depth to which the ointment or gel will easily

penetrate before solidifying." (*Id.* at [0052].) Rolf further discloses that the backing can be "non-porous." (*Id.* at [0192].) In my opinion, a person of ordinary skill in the art would understand that a backing that is non-porous and/or cannot be penetrated is impermeable. I am also of the opinion that a person of ordinary skill in the art would further understand that increasing the amount of sizing agent would increase impermeability.

147. Thus, Wahi '488 alone or in combination with Rolf discloses this limitation.

(e) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless

148. Whatever the scope of the terms "inactivating the particulate matter" and "render said particulate matter harmless," in my opinion, Wahi '488 alone or in view of Rolf discloses this limitation because it discloses killing target organisms (i.e. disinfection rather than just preservation).

149. Wahi '488 is "directed to the prevention of harmful effects caused by airborne contaminants which enter the human nasal passage during breathing." (Ex. 5 at 2:62-64.) Such contaminants include "[m]icro-organisms: viruses, germs, bacteria and fungi." (*Id.* at 3:3-4.) The harmful effects of these contaminants can include "discomforts, allergies and diseases." (*Id.* at 3:4-10.) In my opinion, a person of ordinary skill in the art would understand that preventing the harmful

effects of airborne contaminants can be achieved by killing them before they are able to infect the host.

150. In addition and separately, Wahi '488 in view of Rolf discloses inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless. In particular, Rolf discloses a formulation that effectively kills airborne pathogens. Rolf discloses a formulation containing an ingredient that "effectively ***kill[s] or inactivate[s]*** an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0071] (emphasis added).) Rolf discloses that that ingredient can be an essential oil (*id.* at [0021]), an antimicrobial agent, such as BAC (*id.* at [0252]), and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*Id.* at [0154].) In my opinion, a person of ordinary skill in the art would have been motivated to combine Wahi '488 and Rolf. (Section X.A.a.) Thus, Wahi '488 alone or in view of Rolf discloses inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

B. Independent Claim 2

151. Claim 2 recites "[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the

individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film; b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and c) inactivates the particulate matter and renders said particulate matter harmless." Claim 2 thus is identical to claim 1 except that it claims a formulation rather than a method and includes the following additional limitation: "said formulation comprising at least one cationic agent and at least one biocidic agent." Wahi '488 alone or in view of Rolf renders claim 1 obvious. (Section XII.A.) Wahi '488 further discloses a formulation comprising at least one cationic agent and at least one biocidic agent. In particular, Wahi '488 discloses a positively charged material (Ex. 5 at 5:63-67), which by definition is a cationic agent (Section VII.A). A positively charged material can also have biocidic effects if used in the appropriate concentration. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.)

152. In addition and separately, Rolf discloses a formulation comprising at least one cationic agent and at least one biocidic agent. In particular, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]) and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf

further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*See, e.g., id.* at [0154].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) When BAC and/or lysine hydrochloride are used in sufficient concentrations to act as antimicrobial and/or antiviral agents, they act as biocidic agents. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.)

153. I am further of the opinion that a person of ordinary skill in the art would have been motivated to combine the antimicrobial agent and/or an antiviral agent in Rolf with the nasal formula disclosed in Wahi '488. (Section X.A.a.) This is particularly true given that BAC—the antimicrobial disclosed in Rolf—is also a cationic agent and thus would increase the electrostatic charge of the formula as required by Wahi '488. Thus Wahi '488 alone or in view of Rolf discloses the formulation of claim 1 comprising at least one cationic agent and at least one biocidic agent.

C. Dependent Claim 6

154. Claim 6 recites "[t]he formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride." Wahi '488, alone or in view of Rolf, discloses all the limitations of claim 2. (Section XII.B.)

155. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC. (Ex. 4 at [0252]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this

effect. (*See, e.g., id.* at [0154].) BAC is a cationic agent. (Section VII.B; Ex. 31 at 61; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine the BAC taught in Rolf with Wahi '488's nasal formula. (Section X.A.a.) Thus, Wahi '488 combined with Rolf renders claim 6 obvious.

D. Dependent Claim 7

156. Claim 7 recites "[t]he formulation of claim 2 wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL." Wahi '488, alone or in view of Rolf, discloses all the limitations of claim 2. (Section XII.B.)

157. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]) and/or an antiviral agent, such as lysine hydrochloride. (*Id.* at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*See, e.g., id.* at [0154].) When BAC and/or lysine hydrochloride are used in sufficient concentrations to act as antimicrobial and/or antiviral agents, they act as biocidic agents. (Section VII.A; Ex. 17 at 589, 592; Ex. 19 at 307-308.) A person of ordinary skill in the art would have been motivated to combine the BAC taught in Rolf with Wahi '488's nasal formula. (Section X.A.a.) Thus, Wahi '488 combined with Rolf renders claim 7 obvious.

XI. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID IN VIEW OF BAKER '189 OR BAKER '476 ALONE, OR IN COMBINATION WITH ROLF OR KHALED OR RABE OR KATZ OR WAHI '790

A. Independent Claim 1

(a) A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

158. Whatever the scope of the term "inhibiting harmful particulate matter from infecting an individual," in my opinion, either Baker '189 or Baker '476 alone or in view of Khaled or Rave or Katz or Wahi '790 discloses this limitation because it discloses a formulation applied to skin or tissue of nasal passages of the individual in a thin film, and the described compounds inherently electrostatically attract negatively charged particulate matter.

159. Baker '189 discloses "compositions and methods for decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses." (Ex. 8 at Abstract.) "In certain other embodiments, the compositions of the present invention further comprise one or more cationic halogen containing compounds." (*Id*. at 3:50-53.)

160. Baker '189 discloses "[i]n preferred embodiments, the cationic halogen-containing compound is preferably premixed with the oil phase; however, it should be understood that the cationic halogen-containing compound may be provided in combination with the emulsion composition in a distinct formulation. Suitable halogen containing compounds may be selected, for example, from

compounds comprising chloride, fluoride, bromide and iodide ions." (*Id*. at 17:10-18.) "The nanoemulsions structure of the certain embodiments of the emulsions of the present invention may play a role in their biocidal activity as well as contributing to the non toxicity of these emulsions." (*Id*. at 22:10-13.)

161. Baker '189 discloses the use of QACs including BAC which as explained (*see* Sections VII.A-C.) naturally exhibit cationic and biocidic properties, including electrostatically inhibiting harmful particulate. For example, Baker '189 teaches "Ingredients for use in the non-toxic nanoemulsions include, but are not limited to. . . quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (*Id*. at 30:29-30, 38-40.) Moreover, Baker '189 teaches that the non-toxic nanoemulsions "have antimicrobial activity against most vegetative bacteria (including Gram positive and Gram-negative organisms), fungi, and enveloped and nonenveloped viruses in 15 minutes (e.g., 99.99% killing); and they have sporicidal activity in 1–4 hours (e.g., 99.99% killing) when produced with germination enhancers." (*Id*. at 31:62-67.)

162. Baker '189 discloses nasal administration. "In other embodiments, the contacting is via oral, nasal, buccal, rectal, vaginal or topical administration."

163. Baker '476 is a continuation-in-part to Baker '189 and thus contains the same disclosure as Baker '189, while also disclosing an additional embodiment

comprising CPC and a benzyl ammonium chloride compound (specifically, alkyldimethyl-3,4-dichlorobenzyl ammonium chloride).

164. In addition and separately, Baker '189 or Baker '476 combined with Rolf discloses this element. Rolf discloses a "method for ***preventing*** a respiratory infection" that comprises use of a product "located in the vicinity of the nasal passageway." (Ex. 4 at Claim 1; *see also id.* at Abstract, [0019], [0020], [0021].) In my opinion, a person of ordinary skill in the art would understand the word "preventing" indicates that not even one of the infectious material is allowed to infect the host. Thus, Rolf discloses preventing all particulate matter from infecting an individual through nasal inhalation.

165. I am further of the opinion that a person of ordinary skill in the art would have been motivated to combine Rolf with Baker '189 or Baker '476 to arrive at the claimed invention. ***First,*** Baker '189 or Baker '476 and Rolf describe complementary methods for preventing nasal inhalation of airborne contaminants that cause infection. Baker '189 and Baker '476 disclose a product aimed at "decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens" by using "one or more cationic halogen containing compounds" in an "oil-in-water emulsion comprising quaternary ammonium compound" and is "antimicrobial against bacteria, virus, fungi, and spores" specifically "against most vegetative bacteria (including Gram-positive and Gram-

negative organisms), fungi, and enveloped and nonenveloped viruses" and describes embodiments that can be applied via "nasal…or topical administration." (Ex. 8 at 2:64-66, 3:50-52, 5:2-4, 5:64-6:1, 31:63-65.) Rolf similarly discloses a "method for preventing a respiratory infection" using a formulation that is applied "in the vicinity of the nasal passageway," wherein the formula "kills or inactivates" airborne pathogens. (Ex. 4 at Claim 1, [0252], [0071].) In my opinion, a person of ordinary skill in the art would have recognized the benefit of combining the contaminant killing features of Rolf with the contaminant attracting and trapping features of Baker '189 as doing so would further the Baker '189 goal of decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens.

166. ***Second,*** the teaching of quaternary ammonium compounds, specifically including benzalkonium chloride in Baker '189 would have led a person of ordinary skill in the art to employ the teachings of Rolf relating to the use of benzalkonium chloride. In particular, Baker '189 discloses using a "cationic halogen-containing compound" containing "quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (Ex. 8 at 30:18-40.) Rolf discloses supplementing its primary mode of action (i.e., essential oils) with BAC—a known QAC—as antimicrobial agents to further the goal of preventing pathogens from causing infection. (Ex. 4 at [0153], [0252]; Section VII.A.) A sufficient

concentration of BAC could act as an antimicrobial agent as disclosed in Rolf. (Ex. 17 at 589, 592; Ex. 19 at 307-308.) Up to 0.1% of BAC could be applied to the skin, such a concentration would have biocidic effects. (Section VII.B; Ex. 17 at 589, 592.) Thus, in my opinion, a person of ordinary skill in the art would recognize that QACs as disclosed in Baker '189—and in particular BAC, as discussed in Rolf—could be used not only to absorb contaminants but also to kill contaminants, furthering the disclosed purpose of Baker '189 of decreasing the infectivity of pathogens. (Section VIII.E–H.)

167. Accordingly a person of ordinary skill in the art would have had a reasonable expectation of success in combining Baker '189 and Rolf, as the two systems are complementary and compatible. Thus, Baker '189 or Baker '476 alone or in view of Rolf discloses a method for electrostatically inhibiting all harmful particulate matter from infecting an individual through nasal inhalation.

168. In addition and separately, Baker '189 or Baker '476 combined with Khaled or Rabe or Katz or Wahi '790 renders obvious this claim element. Each of Khaled, Rabe, Katz, and Wahi '790 disclose a film or spray containing QACs (or equivalent cationic compounds) which as explained, inherently are known to have cationic and biocidic properties. (Ex. 9, at [0053] ("The biocide functional groups bonded chemically or physically in the polymer structure, as an auxiliary biocide to the thin film, may include … quaternary ammonia compounds"); Ex. 12, at

Abstract, 8:20-44 ("stabilized electrostatically-sprayable topical compositions" including "Quaternium-18/Benzalkonium Bentonite"); Ex 13, at [0079] (emphasis added) "1.5 fl. oz. (45 ml) of Afrin® moisturizing saline mist solution may be purchased commercially over the counter (Schering-Plough, Memphis, Tenn.). The solution contains water, PEG-32, sodium chloride, PVP, disodium phosphate, sodium phosphate, **benzalkonium chloride**, and disodium EDTA."); Ex. 14, at Abstract ("a nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field' including "one or more electrostatic polymers" such as "poly (dimethyl diallyl ammonium chloride.") *see also sections* VII.A-B, VIII.I-L.)

169. Khaled discloses an "antimicrobial thin film" "having a quaternary ammonium group." (Ex. 9, at [0011-12].) Rabe discloses compositions that are "electrostatically sprayable and are suitably directly applied to the skin." (Ex. 12, at 3:38-39.) Katz discloses nasal sprays including BAC. (Ex. 13, at [0078]-[0081].) And Wahi '790 discloses a "nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field." (Ex. 14, at Abstract.)

170. A POSA would be motivated to combine Baker '189 or Baker '476 with any one of Khaled or Rabe or Katz or Wahi '790 based on the teaching of quaternary ammonium compounds, including benzalkonium chloride. Inclusion of

BAC in Baker '189 would have led a person of ordinary skill in the art to employ the teachings of Khaled or Rabe or Katz or Wahi '790 relating to the use of benzalkonium chloride and other QACs. In particular, Baker '189 discloses using a "cationic halogen-containing compound" containing "quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (Ex. 8 at 30:18-40.) Each of Khaled, Rabe, Katz, and Wahi '790 disclose a film or spray containing QACs (or equivalent cationic compounds) as antimicrobial agents to further the goal of preventing pathogens from causing infection as described in Baker '189. (*See* Section VII.A.) A sufficient concentration of QACs could act as an antimicrobial agent as disclosed in Khaled or Rabe or Katz or Wahi '790. (*See e.g.*, Ex. 17 at 589, 592; Ex. 19 at 307-308.) For example, up to 0.1% of BAC (as disclosed in Baker '189 and Khaled and Katz) could be applied to the skin, such a concentration would inherently have biocidic effects. (Section VII.B; Ex. 17 at 589, 592.) Thus, in my opinion, a person of ordinary skill in the art would recognize that QACs as disclosed in Baker '189—and in particular BAC— could be used not only to absorb contaminants but also to kill contaminants, furthering the disclosed purpose of Baker '189 of decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens. (Section VIII.E–H.)

(b) a formulation is applied to skin or tissue of nasal passages of the individual in a thin film

171. Baker '189 or Baker '476 discloses a formulation that is applied to the skin or tissue of the nasal passages. For example, Baker '189 discloses, among other embodiments, contacting is via oral, **nasal**, buccal, rectal, vaginal or **topical administration**." (Ex. 8, at 5:3-4 (emphasis added).) "[T]he term 'topically' refers to application of the compositions of the present invention to the surface of the skin and mucosal cells and tissues (e.g., alveolar, buccal, lingual, masticatory, or nasal mucosa, and other tissues and cells which line hollow organs or body cavities)." (*Id*. at 13:24-28.) Baker '189 further discloses "topical or nasal spray." (*Id*. at 36:12-16.) Baker '189 further discloses "an oil-in-water emulsion" that is "antimicrobial against bacteria, virus, fungi, and spores." (*Id.* at 5:67-6:1.) In my opinion, a person of ordinary skill in the art would understand that an oil-in-water emulsion can also be applied to the skin inside or around the nasal passage, and would have been motivated to do so given the purpose of Baker '189 of "decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens" (*Id.* at 1:19-21.) I am further of the opinion that a person of ordinary skill in the art would further understand that, when sprays, ointments, or emulsions are applied to the skin, they form a thin film once excess liquid evaporates. (*See also* Section VII.D.)

172. In addition and separately, Baker '189 or Baker '476 in view of Rolf renders obvious this claim element. Rolf discloses a device that is an "ointment or

gel on a backing" and that the formulation can be "embedded" into the backing. (Ex. 4 at [0042], [0026], [0058].) The backing of the patch can "include[] . . . films." (*Id.* at [0198].) The backing can be "about 0.001 mm to about 5.0 mm, about 0.001 mm to about 3.0 mm, or about 0.025 mm to about 1.25 mm." (*Id.* at [0027], [0047].) In my opinion, a person of ordinary skill in the art would understand a film with a 0.001 mm thickness to be a thin film. I am further of the opinion that a person of ordinary skill in the art would have been motivated to combine the teachings of Baker '189 with the teachings of Rolf (Section XI.A.a), and would have understood that making the film as thin as about 0.001 mm would be more comfortable for a person to wear around their nasal passages than a thick film. Thus, Baker '189 alone, or in combination with Rolf, discloses a formulation that is applied to the skin or tissue of nasal passages of the individual in a thin film.

173. In addition and separately, Baker '189 or Baker '476 combined with Khaled or Rabe or Katz or Wahi '790 renders obvious this claim element. Each of Khaled, Rabe, Katz, and Wahi '790 disclose a film or spray containing QACs (or equivalent cationic compounds) which as explained, inherently are known to have cationic and biocidic properties. (Sections VII.A-B; XI.A.a.)

174. Katz and Wahi '790 specifically disclose nasal topical applications (Ex 13, at [0079]; Ex. 14, at Abstract.) Khaled specifically discloses a thin film containing QACs. (Ex. 9, at [0053].)

175. It is my opinion that a person of ordinary skill in the art would have been motivated to combine the teachings of Baker ’189 or Baker ’476 with the teachings of Khaled or Rabe or Katz or Wahi ’790 (Section XI.A.a), and would have understood that a thin film would be more comfortable for a person to wear around their nasal passages than a thick film. Thus, Baker ’189 or Baker ’476 alone, or in combination with Khaled or Rabe or Katz or Wahi ’790, discloses a formulation that is applied to the skin or tissue of nasal passages of the individual in a thin film.

(c) electrostatically attracting the particulate matter to the thin film

176. Baker ’189 or Baker ’476 discloses products that inherently use a positive electrostatic charge to attract negatively charged contaminants. Baker ’189 or Baker ’476 discloses a product that uses a positively charged “cationic halogen containing compound” specifically, “quarternary ammonium compounds (e.g., benzalkonium chloride…” that inherently, due to the cationic properties, attract negatively charged contaminants, and thereby “electrostatically attracting the particulate matter to the thin film.” (Sections VII.A–C; VIII.E–H.) Baker ’189 or Baker ’476 thus inherently disclose electrostatically attracting the particulate matter to the thin film.

(d) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or

tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film

177. Baker ’189 or Baker ’476 discloses binding contaminants to the thin film. In particular, Baker ’189 or Baker ’476 discloses “topical or nasal spray.” (Ex. 8, at 36:12-16) including “an oil-in-water emulsion” that is “antimicrobial against bacteria, virus, fungi, and spores.” (*Id.* at 5:67-6:1.) In my opinion, a person of ordinary skill in the art would understand that an oil-in-water emulsion can also be applied to the skin inside or around the nasal passage and would have been motivated to do so given the purpose of Baker ’189 of “decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens” (*Id.* at 1:19-21.) I am further of the opinion that a person of ordinary skill in the art would also understand that when sprays, ointments, or emulsions are applied to the skin, they form a thin film once excess liquid evaporates. (*See also* Section VII.D.)

178. Baker ’189 or Baker ’476 further discloses adjusting the adhesion of the thin film so that the thin film sticks to the skin or tissue, as well as adjusting the cohesion of the thin film so that it is impermeable. In particular, Wadstrom discloses:

> For topical applications, the pharmaceutically acceptable carrier may take the form of a liquid, cream, foam, lotion, or gel, and may additionally comprise organic solvents, emulsifiers, gelling agents, moisturizers, stabilizers, surfactants, wetting agents, preservatives, time release agents, and minor amounts of humectants, sequestering agents, dyes, perfumes, and other components commonly employed in pharmaceutical compositions for topical administration.

(Ex. 8, at 36:31-39.) In my opinion, a person of ordinary skill in the art would understand that a nasal spray or topical application, ointment, or emulsion that is applied to the skin is intended to stick to the skin or tissue and would adjust the viscosity (and thereby the adhesion) of the formulation in order to achieve that intended purpose. (Section VII.D.) I am also of the opinion that because the contaminants are absorbed and bound by the support matrix and the support matrix sticks to the skin, the contaminants are held in place.

179. Given that the disclosed purpose of Baker ’189 or Baker ’476 is “decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens” (Ex. 8, at 1:19-21.), in my opinion, a person of ordinary skill in the art would adjust the viscosity (and thereby the impermeability) of the formulation in order to achieve the intended purpose of preventing any contaminants from contacting the skin.

180. In addition and separately, Baker ’189 or Baker ’476 combined with Rolf discloses this limitation. In particular, Rolf discloses that a formulation that

includes a "pressure sensitive adhesive 14" that enables the device to be "placed upon the skin of a patient" and stay in "continuous contact with the skin surface." (Ex. 3 at [0107], [0041], [0116].) The amount of pressure sensitive adhesive can be adjusted to effectively provide the "requisite adhesiveness." (*Id.* at [0109]; *id.* at [0110] (listing exemplary range of adhesion adjustment based on a specific adhesive material).)

181. Rolf further discloses adjusting cohesion to provide adequate impermeability to the thin film. Rolf discloses "an ointment or gel on a backing" wherein "use of a backing material that has been treated with a sizing agent allows for the effective control of the rate of penetration, such that the gel or ointment has solidified after it has begun to penetrate the backing, but before it has passed completely through the backing." (Ex. 4 at [0042], [0052].) Rolf further discloses that "the use of a backing material that has been treated with a sizing agent allows for the effective control of the depth to which the ointment or gel will easily penetrate before solidifying." (*Id.* at [0052].) Rolf further discloses that the backing can be "non-porous." (*Id.* at [0192].) In my opinion, a person of ordinary skill in the art would understand that a backing that is non-porous and/or cannot be penetrated is impermeable. I am also of the opinion that a person of ordinary skill in the art would further understand that increasing the amount of sizing agent would increase impermeability. A person of ordinary skill in the art would have been

motivated to combine the impermeability feature taught by Rolf with the electrostatic formula taught by Baker ’189 or Baker ’476 to ensure that any contaminants captured by the formula do not come in direct contact with the skin. Thus, Baker ’189 or Baker ’476 alone or in view of Rolf discloses holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film.

182. In addition and separately, Baker ’189 or Baker ’476 combined with Khaled or Rabe or Katz or Wahi ’790 renders obvious this claim element. Each of Khaled, Rabe, Katz, and Wahi ’790 disclose a film or spray containing QACs (or equivalent cationic compounds) which as explained, inherently are known to have cationic and biocidic properties that electrostatically attract particulate matter. (Sections VII.A-B; VIII.H-K; XI.A.a.) Thus, Baker ’189 or Baker ’476 alone or in view of Khaled or Rabe or Katz or Wahi ’790 discloses holding the particulate matter in place.

(e) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless

183. Whatever the scope of the terms “inactivating the particulate matter” and “rendering harmless,” in my opinion, Baker ’189 or Baker ’476 alone or in view of Rolf discloses this limitation because it discloses killing target organisms (i.e. disinfection rather than just preservation).

184. The disclosed purpose of Baker '189 or Baker '476 is "decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens" (Ex. 8, at 1:19-21.) Baker '189 or Baker '476 further discloses using members of a "quaternary ammonium group" to create the requisite positive charge. (*Id*. at 22:10-13, 30:29-30, 38-40, 31:62-67; *see also* Section XI.A.a.) Sufficient quantities of QACs have not only cationic properties but also can kill contaminants. (Section VII.A; Ex. 87 at 589, 592; Ex. 89 at 307-308.) In my opinion, a person of ordinary skill in the art would be motivated to use a sufficient concentration of QACs to kill contaminants given the purpose of Baker '189 or Baker '476 of addressing "decreasing the infectivity, morbidity, and rate of mortality associates with a variety of pathogens" (Ex. 8, at 1:19-21.) A person of ordinary skill in the art would understand that Baker '189 or Baker '476 would more effectively achieve its intended purpose if contaminants bound outside the nose were killed so that they do not concentrate outside the nose and/or inadvertently get wiped into the nose in an active state.

185. In addition and separately, Baker '189 or Baker '476 combined with Rolf discloses this element. Rolf discloses a formulation containing an ingredient that "effectively ***kill[s] or inactivate[s]*** an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0071] (emphasis added).) Rolf discloses that that ingredient can be an essential oil (*id*. at [0021]), an antimicrobial

agent, such as BAC (*id.* at [0252]), and/or an antiviral agent, such as lysine hydrochloride (*id.* at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*Id.* at [0154].) In my opinion, a person of ordinary skill in the art would have been motivated to combine Baker '189 or Baker '476 and Rolf and would have had a reasonable expectation of success in doing so. (Section XI.A.a.) Thus, Baker '189 or Baker '476 alone or in view of Rolf discloses inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

186. In addition and separately, Baker '189 or Baker '476 combined with Khaled or Rabe or Katz or Wahi '790 renders obvious this claim element. Each of Khaled, Rabe, Katz, and Wahi '790 disclose a film or spray containing QACs (or equivalent cationic compounds) and exhibiting antimicrobial properties or restrict the flow of air contaminants, and as explained, inherently are known to have cationic and biocidic properties that electrostatically attract particulate matter. (Sections VII.A-B; VIII.H-K; XI.A.a.) Thus, Baker '189 or Baker '476 alone or in view of Khaled or Rabe or Katz or Wahi '790 discloses inactivating the particulate with an ingredient that renders it harmless.

B. Independent Claim 2

187. Claim 2 recites "[a] formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation

wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied: a) electrostatically attracts the particulate matter to the thin film; b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and c) inactivates the particulate matter and renders said particulate matter harmless." Claim 2 thus is identical to claim 1 except that it claims a formulation rather than a method and includes the following additional limitation: "said formulation comprising at least one cationic agent and at least one biocidic agent." Baker '189 or Baker '476 alone or in view of Rolf renders claim 1 obvious. (Section XI.A.)

188. Baker '189 or Baker '476 further discloses a formulation comprising at least one cationic agent and at least one biocidic agent. In particular, Baker '189 or Baker '476 discloses a "[i]ngredients for use in the non-toxic nanoemulsions include, but are not limited to. . . quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (Ex. at 30:29-30, 38-40.)

189. Baker '476 is a continuation-in-part to Baker '189 and thus contains the same disclosure as Baker '189, while also disclosing an additional embodiment comprising CPC and a benzyl ammonium chloride compound (specifically,

alkyldimethyl-3,4-dichlorobenzyl ammonium chloride). (Ex. 9, at [0232].)

190. A QAC can have biocidic effects if used in the appropriate concentration. (Section VII.A; Ex. 87 at 589, 592; Ex. 89 at 307-308.) Thus Baker '189 or Baker '476 discloses the formulation of claim 1 comprising at least one cationic agent and at least one biocidic agent.

191. In addition and separately, Baker '189 or Baker '476 combined with Rolf discloses this element. Rolf discloses a formulation containing an ingredient that "effectively **kill**[s] or **inactivate**[s] an airborne pathogen, a respiratory tract pathogen, or a combination thereof." (Ex. 4 at [0071] (emphasis added).) Rolf discloses that that ingredient can be an essential oil (*id*. at [0021]), an antimicrobial agent, such as BAC (*id*. at [0252]), and/or an antiviral agent, such as lysine hydrochloride (*id*. at [0153]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (*Id*. at [0154].) In my opinion, a person of ordinary skill in the art would have been motivated to combine Wadstrom and Rolf and would have had a reasonable expectation of success in doing so. (Section XI.A.a.)

192. In addition and separately, Baker '189 or Baker '476 combined with Khaled or Rabe or Katz or Wahi '790 renders obvious this claim element. Each of Khaled, Rabe, Katz, and Wahi '790 disclose a film or spray containing QACs (or equivalent cationic compounds) and exhibiting antimicrobial properties or

restricting the flow of air contaminants, and as explained, inherently are known to have cationic and biocidic properties that electrostatically attract and render harmless particulate matter. (Sections VII.A-B; VIII.H-K; XI.A.a.)

C. Dependent Claim 6

193. Claim 6 recites "[t]he formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride." Baker '189 or Baker '476, alone or in view of Rolf, anticipates or renders claim 2 obvious. (Section XI.B.)

194. Baker '189 or Baker '476 further discloses "quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%]." (Ex. 8, at 30: 38-40.) I understand that a "dependent" claim refers back to a prior claim and incorporates all of the limitations of the claim from which it depends. BAC is a member of the "quaternary ammonium group." (Ex. 31 at 61.) A sufficient BAC concentration could be used to attract contaminants, furthering the disclosed purpose of Baker '189 or Baker '476 of "decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses." (Section VII.A.)

195. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]). Rolf further requires that the ingredient be present in an "appropriate and suitable amount" to realize this effect. (See, e.g., id. at [0154].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine

the BAC taught in Rolf with Baker ’189 or Baker ’476’s nasal embodiments. (Section XI.A.a.) Thus, Baker ’189 or Baker ’476 combined with Rolf discloses the formulation of claim 2 wherein the at least one cationic agent is BAC.

196. In addition and separately, Katz discloses a nasal spray including BAC. (Ex 13, at [0079].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine the BAC in nasal spray taught in Katz with Baker ’189 or Baker ’476’s nasal embodiments. (Section XI.A.a.) Thus, Baker ’189 or Baker ’476 combined with Katz discloses the formulation of claim 2 wherein the at least one cationic agent is BAC.

D. Dependent Claim 7

197. Claim 7 recites “[t]he formulation of claim 2 wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.” Baker ’189 or Baker ’476, alone or in view of Rolf, anticipates or renders claim 2 obvious. (Section XI.B.)

198. Baker ’189 or Baker ’476 further discloses “quaternary ammonium compounds (e.g., benzalkonium chloride [0.5–2%].” (Ex. 8, at 30: 38-40.) I understand that a “dependent” claim refers back to a prior claim and incorporates all of the limitations of the claim from which it depends. BAC is a member of the “quaternary ammonium group.” (Ex. 31 at 61.) A sufficient BAC concentration

could be used to attract contaminants, furthering the disclosed purpose of Baker ’189 or Baker ’476 of “decreasing the infectivity, morbidity, and rate of mortality associated with a variety of pathogenic organisms and viruses.” (Section VII.A.)

199. In addition and separately, Rolf discloses a formulation containing an antimicrobial agent, such as BAC (Ex. 4 at [0252]). Rolf further requires that the ingredient be present in an “appropriate and suitable amount” to realize this effect. (See, e.g., id. at [0154].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine the BAC taught in Rolf with Baker ’189 or Baker ’476’s nasal embodiments. (Section XI.A.a.) Thus, Baker ’189 or Baker ’476 combined with Rolf discloses the formulation of claim 2 wherein the at least one cationic agent is BAC.

200. In addition and separately, Katz discloses a nasal spray including BAC. (Ex 13, at [0079].) BAC is a cationic agent. (Section VII.B; Ex. 1039 at 6.) A person of ordinary skill in the art would have been motivated to combine the BAC in nasal spray taught in Katz with Baker ’189 or Baker ’476’s nasal embodiments. (Section XI.A.a.) Thus, Baker ’189 or Baker ’476 combined with Katz discloses the formulation of claim 2 wherein the at least one cationic agent is BAC.

SUBJECT MATTER ELLIGIBILITY

XII. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR BEING DIRECTED TO INELEGIBLE SUBJECT MATTER UNDER 35 U.S.C. § 101

201. I understand that patent claims directed at laws of nature, natural phenomena, and/or abstract ideas that do not contain elements sufficient to ensure that the patent in practice amounts to significantly more than a patent upon an ineligible concept, are not eligible for patent protection and are invalid.

202. The ’802 Patent is directed to the effects of a law of nature or a natural phenomena, namely the principle that like charges repel each other, while unlike charges attract, e.g., a positive charge attracts a negative charge. While the Challenged Claims of the ’802 patent recite additional elements, each of those additional claim elements are either conventional steps that are well known to a POSA or depend on the very same law of nature or natural phenomena. Thus, in my opinion, the ’802 Patent claims do not recite any inventive concept that would transform the law of nature into a patent eligible invention.

203. More specifically, the limitation in independent claims 1 and 2 of “electrostatically [attracting/attracts] the particulate matter to the thin film” is directed to the naturally occurring process whereby negatively and positive charged elements are naturally attracted to each other. As such, claims 1 and 2 (in addition to claims 6 and 7, which depend from claim 2), are directed to and claim

a result or effect (electrostatic attraction) that itself is a law of nature or a natural process, under the first step of the § 101 test.

204. The ’802 Patent Abstract reinforces this concept, stating that the claimed invention, “when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge . . . .” The ’802 Patent further explains that by creating “an electrostatic field in an area near” the nasal passages “reduce[s] the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body.” ’802 Patent at 1:66 – 2:2. The ’802 Patent also explains that the object of the claimed invention is “achieved by an electrostatically charged composition . . . which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped.” ’802 Patent at 3:33-38.

205. With respect to the second step of the § 101 test, it is also my opinion that each of the additional elements of the Challenged Claims recite nothing more than well-understood, routine and conventional activity or are directed to the very same law of nature or natural phenomena.

206. For example, a POSA would understand the desire to adjust “the adhesion of the thin film to permit said thin film to stick to the skin or tissue,” and the ’802 Patent specification and claims do not provide any further guidance as to

how to do this or any unique method for doing so. Likewise, the claim element of "inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless" is also directed to well-understood, routine, and conventional activity. As explained above QACs were known to have antimicrobial properties since the 1930s, and BAC is likewise a well-known and commonly used disinfectant.

207. Moreover, each of the additional claim limitations are provided at only a general level, as opposed to describing a specific application of the natural law/phenomena. For example, there is no mention in the '802 patent claims as to: (1) the specific charge density or other quantitative parameters that will be needed to create the electrostatic field; (2) what magnitude of electrostatic field is necessary to attract oppositely charged contaminants; (3) how far the electrostatic field needs to be from the application surface; (4) how much of the product must be applied to be effective; or (5) how long the composition must stay on the skin to be effective. In other words, the '802 patent claims simply rely on the general presence of the electrostatic field/natural phenomena to achieve the claimed result and function.

208. In addition, the additional claim limitations do not describe an inventive concept beyond the law of nature/natural phenomena. Notably, the '802 patent describes the claimed invention as "electrostatically charged nasal

application products [that] capture and hold the contaminants including viruses, bacterial, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless." '802 patent at 2:3-7.

209. The use of QACs and BAC to inactivate and render such contaminants harmless was well-understood, routine and conventional activity, for the reasons provided earlier in this report. Further, to the extent the inventive concept of the claims is provided by the understanding or discovery that the law of nature/natural phenomena can be used to electrostatically attract particulate matter to prevent it from infecting an individual, that concept was already disclosed in the inventor's own prior art.

210. For example, Wahi '488 describes the use of an "electrostatic material" that creates an "artificial electrostatic field in an area near a human nasal passage," "restrict[s] the inhalation of airborne contaminants," and "prevent[s] the contaminants in coming in direct contact with the skin" (Wahi '488 at 3:12-13, 3:21-23, 3:25-28, 3:31-34) for the purpose of restricting the flow of airborne contaminants into nasal passages (Wahi '488 at 3:50-57, claim 1). Wahi '488 also explains that as a result of the artificial electrostatic field created by the product, airborne contaminants will be "attracted to and adhere" to the product. Wahi '488 at 7:12-25. Similarly, Wahi '481 describes a "product and method for restricting

the flow of airborne contaminants into a nasal passage" that "involves creating an electrostatic field in an area near a nasal passage." Wahi '481 at Abstract.

211. For all of the foregoing reasons, it is my opinion that the claims 1, 2, 6 and 7 of the '802 patent are directed toward the effects of a law of nature or natural phenomena, and all other claimed aspects are directed to that same law of nature/natural phenomena or other well-understood, routine, and conventional activity.

CREDIBLE UTILTY, WRITTEN DESCRIPTION, AND ENABLEMENT

XIII. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF CREDIBLE UTILITY

212. It is my opinion that claims 1, 2, 6, and 7 are invalid under 35 U.S.C. §§ 101/112 for lack of credible utility.

213. As an object of the claimed invention, the '802 Patent states that "to accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied." '802 patent at 4:39-43.

214. A person skilled in the art reading the '802 patent specification, however, would understand that while the '802 patent does provide a laundry list of possible formulations, it does not include any data or test results for any of the formulations described, demonstrating to a person skilled in the art that there is a

substantial likelihood that the claimed invention will work by "electrostatically attracting" particulate matter to a thin film applied to the nasal passages and holding the particulate matter in place through adhesion to the thin film in order to electrostatically inhibit such harmful particulate matter from infecting an individual. Nor does the '802 patent even provide any discussion or suggestion of what types of tests or procedures could be employed by a person skilled in the art to determine whether such formulations would work as described and claimed. Finally, the '802 patent also does not include any explanation or suggestion that the claimed invention is likely to work based on any similarities or analogies to other compositions or formulations that are known to work in a similar manner.

215. While the '802 patent claims also purport to inactivate particulate matter and render said particulate matter harmless through use of a cationic agent such as BAC, it was well known to persons skilled in the art for decades prior to the date of the invention that QACs, including BAC, have antimicrobial and disinfectant properties.

216. As such, in my opinion, apart from its reliance on the previous and well-known properties of cationic agents such as QACs and BAC, the '802 Patent provides no other information to a person skilled in the art to support the assertion that the claimed invention also works by "electrostatically inhibiting" harmful particulate matter from infecting an individual. In other words, a person skilled in

the art reading the '802 Patent specification would understand that it does not provide anything other than a hypothesis that the claimed invention operates to "electrostatically inhibit" harmful particulate matter from infecting an individual.

217. For all of the foregoing reasons, it is my opinion that a person skilled in the art would not credibly believe the statements in the '802 Patent that the claimed invention operates by "electrostatically inhibiting" harmful particulate matter from infecting an individual. No evidence was presented in the '802 patent specification to demonstrate that the claimed invention will have the claimed effects, and without any corroborating data or test results, a person skilled in the art would not believe the claimed invention to work in the manner alleged in the patent.

XIV. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF ENABLEMENT

218. It is my opinion that the '802 patent specification does not teach a person skilled in the art how to make or use the claimed invention without undue experimentation. In addition, claims 1, 2, 6 and 7 of the '802 patent are extremely broad and the specification does not enable the full scope of the claims.

A. Nature of the Invention and State of the Prior Art

219. As described previously, the '802 Patent purports to describe the use of previously known formulations, but for the purpose of "electrostatically inhibiting harmful particulate matter from infecting an individual. '802 Patent at

1:62-67 (claimed invention "relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed").

220. The '802 Patent also describes prior art patents addressing electrostatically charged compositions, but noting that "those compositions simply create an electrostatic field that helps to filter out oppositely charged materials" and that "[w]hile this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream." '802 Patent at 2:42-52. As such, the '802 Patent admits that the manner in which the claimed invention is purported to operate is not expressly disclosed or taught in the prior art.

B. Breadth of the Claims

221. Asserted independent claims 1 and 2 of the '802 Patent are extremely broad. Claim 1 broadly recites a method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein "a formulation" is applied to skin or tissue. As such, claim 1 broadly encompasses

any formulation, with any components in any combination, that achieves the claimed result.

222. Claim 2 is also extremely broad, adding only the limitation that "said formulation [comprises] at least one cationic agent and at least one biocidic agent," thereby broadly encompassing any cationic agent and/or biocidic agent in any combination or range that achieves the claimed result.

223. Dependent claims 6 and 7 add the further limitation where the cationic agent is Benzalkonium Chloride or Lysine HCL. More specifically, claim 2 uses "comprising" language, which I understand to mean that the claims can cover any formulation that includes at least one cationic agent (e.g., BAC) and at least one biocidic agent, but that the formulation can include any number of other components in any range, as long as the formulation still achieves the claimed result.

C. Amount of Direction or Guidance in the '802 Patent Specification and Presence/Absence of Working Examples

224. While the '802 Patent contains a large list of possible formulations and components that are purportedly within the scope of the claimed invention, the patent does not teach or disclose which combinations or percentages of the different components are necessary to provide the claimed functionality of

"electrostatically inhibiting" harmful particulate matter from infecting an individual.

225. For example, the '802 Patent includes ten separate tables, each with numerous formulations and compounds that are variable. The '802 Patent further states:

> All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

(Ex 1., at 10:7-17.)

226. As explained above, the '802 Patent does not provide any examples that include the results of any testing of any of the disclosed formulations, let alone any guidance as to what types of tests should be conducted in order to determine whether a particular formulation would "operate in the manner" disclosed, e.g., by electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Nor does the '802 Patent provide any examples or any

guidance as to how the percentages of components can be varied while still achieving "the same results."

227. Indeed, the '802 Patent even acknowledges that varying the percentages of the ingredients can affect the potency of the formulation and the consistency of the formulation. A person skill in the art would understand that both of these attributes could impact the ability of the formulation to "render said particulate material harmless" and the claimed adhesive and electrostatic properties of the formulation. The '802 Patent, however, does not provide any explanation or guidance as to how or to what degree "[v]arying the percentages for the active ingredients affects the potency of the formulation." Nor does the '802 Patent provide any explanation or guidance to how or to what degree "[v]arying the percentages for the inactive ingredients affects the consistency of the formulation."

228. In addition, the '802 patent fails to provide any information concerning the specific charge density or other quantitative parameters that will be needed to create the electrostatic field, what magnitude of electrostatic field is necessary to attract oppositely charged contaminants, how far the electrostatic field

needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective.

D. Level of Skill in the Art and Unpredictability of the Art

229. As explained above, a person of ordinary skill in the art in the field related to the ’802 Patent would be someone who had at least a M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation.

230. In addition, the ’802 Patent also acknowledges that the manner in which the claimed invention is purported to operate is not expressly disclosed or taught in the prior art. As such, in my opinion, there is a relatively high level of unpredictability associated with the claimed invention described in the ’802 patent, particularly in view of the lack of disclosure and guidance in the ’802 patent as to how to make and use the claimed invention.

E. Quantity of Experimentation Required

231. In my opinion, a person skilled in the art reading the ’802 patent would need to undertake extensive and undue experimentation to make and use the claimed invention.

232. For example, although the ’802 Patent specification makes the conclusory statement that the “desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue

experimentation," in my opinion that statement is inconsistent with the countless formulations presented in Tables 1-10 and the lack of any guidance as to how to test any possible formulations for the claimed activity. Not only would a POSA need to test voluminous formulations with countless combinations and variability, but a POSA would also need to develop his/her own testing protocol to determine "potency" and "consistency" of the myriad of formulations. Likewise, a POSA would also need to develop his/her own testing protocols to assess whether any of these countless formulations operate to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation.

233. Without any guidance from the '802 Patent, this process of creating a test protocol to determine efficacy and consistency, and then using that created test to evaluate countless different variations of the possible formulations presented in Tables 1-10 would involve extensive and undue experimentation, notwithstanding the '802 Patent's conclusory statements stating otherwise. This exercise would be extensive and undue, particularly in view of the fact that the '802 Patent provides no guidance whatsoever as to which components of the formulation can be varied, or by how much, without changing the function or operation of the formulation.

234. Likewise, in view of the fact that the '802 patent provide no guidance to a POSA as to the specific charge density or other quantitative parameters that will be needed to create the electrostatic field, what magnitude of electrostatic field

is necessary to attract oppositely charged contaminants, how far the electrostatic field needs to be from the application surface, how much of the product must be applied to be effective, or how long the composition must stay on the skin to be effective, a POSA would need to undertake extensive and undue experimentation to modify and test each of these variables in order to determine how to effectively make and use the claimed invention. There is also no specific test or testing protocol provided to inform a person of ordinary skill in the art if the product formulated would be effective in achieving the goals of the invention or not.

235. In summary, it is my opinion that in view of the nature of the invention, the breadth of the claims, and the lack of any direction or guidance presented in the specification, including the lack of any testing protocols that a person skilled in the art could use to determine whether a particular formulation will work, such person would need to engage in extensive and undue experimentation in order to make or use the full scope of the claimed invention.

XV. ANALYSIS: CLAIMS 1, 2, 6, AND 7 ARE INVALID FOR LACK OF ADEQUATE WRITTEN DESCRIPTION

236. It is my opinion that the ’802 patent specification does not reasonably convey to a person skilled in the art that the inventor was in possession of any formulation or composition that would operate in the manner claimed in the ’802 patent as of the filing date of the application.

237. While the ’802 patent specification describes numerous formulations and different ranges of components that are purportedly within the scope of the claimed invention, the specification provides no data or testing of any kind demonstrating to a person of skilled in the art that the mere fact of applying a thin film having a positive charge will operate to “electrostatically attract” negatively charged particulate matter, adhering such particulate matter to the thin film, thereby inhibiting the particulate matter from infecting an individual. Nor does the ’802 patent specification provide any indication to a person skilled in the art that the inventor even tested any of the formulations disclosed in the patent to assess whether they actually operate to electrostatically inhibit harmful particulate matter from infecting an individual through nasal inhalation. In other words, a person skilled in the art reading the ’802 patent would understand that the inventor merely had a wish or hope that the claimed invention would operate in the manner described.

238. More specifically, the ’802 Patent provides ten separate tables, each with many listed components and percent ranges, yet provides no data explaining which formulations will operate to electrostatically attract oppositely charged particulate matter. Nor is there any explanation or disclosure within the ’802 Patent that would demonstrate to a person skilled in the art that the mere fact of electrostatically inhibiting such particulate matter will be sufficient to render such

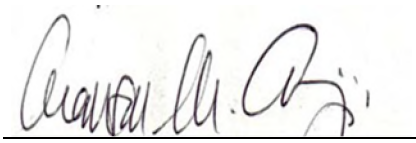
particulate matter harmless. Particularly in view of the countless formulations and variable components encompassed by the claims, the specification of the ’802 Patent would not indicate to a POSA that the inventors possessed the claimed subject matter.

XVI. CONCLUSION

239. For the aforementioned reasons, in my opinion, to person of ordinary skill in the art as of the alleged Priority Date of the ’802 Patent, the Challenged Claims of the ’802 Patent are invalid for each of the reasons explained herein.

Date: June 27, 2022

Respectfully submitted,



Mansoor M. Amiji, Ph.D.

CERTIFICATE OF SERVICE

I certify that on June 27, 2022, I served the foregoing document and this Certificate of Service on Counsel for Plaintiff via email. A copy is also being mailed via First Class Mail to:

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EXHIBIT 2

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

RESPONSIVE EXPERT REPORT OF MANSOOR M. AMIJI, PH.D. ON NON-INFRINGEMENT

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I, Dr. Mansoor M. Amiji, submit this Responsive Expert Report as follows:

1. My name is Mansoor M. Amiji.

2. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned district court patent litigation case, with case number 2:21-cv-10312-SJM-RSW. I am being compensated for my time in connection with this litigation at my standard consulting rate of $900 per hour. My compensation is not affected by the outcome of this matter.

3. I have been informed that Trutek has accused BlueWillow's NanoBio Protect® product of infringing claims 1, 2, 6 and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent"). I have reviewed the three reports served by Trutek and prepared by Dr. Edward Lemmo, Dr. Alexei Ermakov and Mr. Shane Burns, and have been asked to provide my opinions and analysis as to the matters addressed therein with respect to whether NanoBio Protect® satisfies each element of claims 1, 2, 6, and 7 (the "Asserted Claims") of the '802 Patent. My analysis and opinions provided herein are limited to the Challenged Claims, and I reserve the right to amend and/or update my analysis and opinions should Trutek assert additional claims in this litigation.

4. This report sets forth the opinions that I have formed based on the information available to me as of the date below. The opinions and facts set forth

in this report are based upon the information described in this report, as well as my analysis of the asserted patent, Trutek's expert reports, the state of the art at the time of the invention, as well as my knowledge and experience in the relevant field. It is my understanding that expert discovery is ongoing. I reserve the right to supplement or amend this report based on additional information made available to me, including in light of any expert reports or other responses to the subject matter addressed herein.

5. I expect to be called to testify at trial in the above-captioned action. If called upon, I am prepared to testify about my background, qualifications, and experience, as well as about the issues set forth in this report. If I am called upon to testify at trial, I may rely on exhibits and/or visual aids to demonstrate the bases for my opinions. I have not yet prepared any such exhibits or visual aids. I also reserve the right to provide a tutorial relating to the general topics contained in this report.

6. I am not currently and have not at any time in the past been an employee of BlueWillow. I have no financial interest in BlueWillow.

I. QUALIFICATIONS AND EXPERIENCE

7. I am an expert in the field of pharmaceutical sciences and drug formulation development and characterization. Specifically, I specialize in drug formulation development and targeted delivery of therapeutics, and I have been an

expert in this field since prior to July 7, 2008. I have relied upon my training, knowledge, and experience in the relevant art to form my opinions.

8. In 1988, I graduated with honors from Northeastern University and received a Bachelor of Science degree in Pharmacy and became a Registered Pharmacist in Massachusetts. In 1992, I received a Ph.D. in Pharmaceutical Science/Pharmaceutics from the School of Pharmacy and Pharmaceutical Sciences at Purdue University, under the supervision of Professor Kinam Park. My dissertation focused on biomaterials and water-soluble polymers. During my graduate studies at Purdue University, I took several pharmaceutics courses and had hands-on training in pharmaceutical formulation development and characterization.

9. After receiving my Ph.D. in 1992, I worked as a Senior Research Scientist for Columbia Research Laboratories (CRL) in Madison, Wisconsin. At CRL, I worked on polymeric delivery systems for various types of therapeutic agents, including those administered topically to skin and mucosal surfaces.

10. I am currently the University Distinguished Professor and Professor of Pharmaceutical Sciences in the School of Pharmacy, Bouve College of Health Sciences at Northeastern University in Boston, Massachusetts. I am also jointly appointed as a Professor of Chemical Engineering in the College of Engineering at Northeastern University. I am also currently an Affiliate Faculty Member in the

Department of Biomedical Engineering at Northeastern University. I have taught and carried out research in pharmaceutical sciences at Northeastern University since 1993, and from 2010 to 2016, I served as the Chairman of the Department of Pharmaceutical Sciences. In 2000, I was a Visiting Research Scholar in the Department of Chemical Engineering at the Massachusetts Institute of Technology (MIT) in Cambridge, Massachusetts, in the laboratory of Professor Robert Langer.

11. As a tenured faculty member at Northeastern University, I have over 29 years of experience in teaching drug formulations to both graduate and undergraduate students. In theory and laboratory courses that I have taught and continue to teach, I extensively cover the manufacturing and composition of pharmaceutical formulations, delivery systems and pharmacokinetics. I also serve as a consultant to several pharmaceutical, biotechnology, and medical device companies regarding product development and drug delivery.

12. I lecture extensively on various topics at the leading edge of modern pharmaceutical sciences, and I regularly attend numerous worldwide pharmaceutical conferences. I have been an invited speaker at national and international scientific conferences.

13. Over the course of my career, I have published extensively and am ranked as a Thompson-Reuters Highly Cited (top 1%) author in Pharmacology and Toxicology. I have coauthored over 60 book chapters and more than 350 peer

reviewed scientific articles. I am also an inventor on several issued United States patents. The topics of these materials including the design and development of pharmaceutical dosage forms, pharmacokinetics, drug metabolism, dose delivery and controlled research systems and the use/formulation of related excipients and methods. I have been involved in and consulted on multiple projects over the years both in industry and academia about the aforementioned topics. To that end, I have taught courses in pharmaceutics; drug design, evaluation, and development; dosage forms; and pharmacokinetics.

14. I have served as a grant reviewer for the National Institutes of Health, the Department of Defense, the United States Department of Agriculture, and the American Chemical Society. I am a member of several professional and industrial societies, including the American Association of Pharmaceutical Sciences (AAPS) and the Controlled Release Society (CRS), and have participated as a reviewer for more than 50 scientific journals.

15. I have also received a number of professional awards and honors, including the Nano Science and Technology Institute (NSTI) Fellowship Award for Outstanding Contributions towards the Advancement in Nanotechnology, Microtechnology, and Biotechnology in 2006; a Fellowship and Meritorious Manuscript Award from the AAPS in 2007; the Tsuneji Nagai Award from the CRS in 2012; the Northeastern University School of Pharmacy Distinguished Alumni

Award in 2016; and Purdue University College of Pharmacy Distinguished Alumni Award in 2019. Over the course of my career, I have advised numerous post-doctoral associates, doctoral students, master's students, visiting scientists, and research fellows.

16. I am a founder and scientific advisor to many pharmaceutical companies, including Nemucore Medical Innovations and Targagenix, Inc., which have licensed our patents on lipid-based drug delivery systems and is in the process of developing commercial products.

17. I was appointed as a Fellow of the American Association of Pharmaceutical Scientists (AAPS) in 2007 and serve as a long-term member of the Association. I am also a Fellow of the Controlled Release Society (CRS) since 2014 and serve on the Scientific Advisory Board of the CRS. I have also served as a permanent member of the National Institutes of Health's grant review panel and many other public funding agencies in the U.S. and across the world. I am an Editor of the journal Drug Delivery and Translational Research and Associate Editor of several peer-reviewed journals and on the editorial board of about a half dozen other scientific journals.

18. Additional details concerning my background, training and experience are contained in my current *Curriculum Vitae*, attached as Exhibit 1.

19. Based on my education, training, and experience, including my research expertise in pharmaceutical product development and drug formulation development of over 29 years, including in the July 7, 2008 time frame, I am qualified to provide technical analysis and opinions regarding the subject matter of this case and the '802 Patent.

20. The matters in which I have testified in the past four years include:

- *iCeutica Private, LTD et al. v. Lupin Limited et al.*, C.A. No. 1:14-cv-01515-SLR-SRF (D. Del.)
- *Mylan Pharmaceuticals Inc. v. Allergan, Inc.*, C.A. No. IPR2016-01127, -1128, -1129, -1130, -1131, -1132 (PTAB)
- *Lipocine, Inc. v. Clarus Therapeutics, Inc.*, Patent Interference No. 106,045 (McK)
- Cadence Pharmaceuticals Inc., et al. v. InnoPharma Licensing LLC, et al., C.A. No. 1:14-cv-01225-LPS (D. Del.)
- *Impax Laboratories, Inc. v. Actavis Laboratories FL, Inc. et al.*, C.A. No. 2:2015-cv-06934 (D.N.J.)
- R*eckitt Benckiser LLC v. Aurobindo Pharma Limited*, C.A. No. 14-cv-1203-LPS (D. Del.)
- *AMAG Pharmaceuticals, Inc. v. Sandoz, Inc.*, C.A. No. 16-1508-PGS-LHG (D.N.J.)
- *Alcon Research, Ltd. v. Watson Laboratories. Inc.*, C.A. No. 16-129-LPS-SRF (D. Del.)
- *Onyx Therapeutics, Inc. v. Cipla Limited, et al.*, C.A. No. 16-988-LPS (D. Del)
- *Almirall, LLC v. Taro Pharmaceutical Industries Ltd.*, C.A. No. 17-663-JFB-SRF (D. Del.)
- *Galderma Labs. LP v. Teva Pharmaceuticals USA, Inc.*, C.A. No. 17-1783-RGA (D. Del.)
- *FWK Holdings LLC v. Shire PLC et al.*, C.A. No. 16-cv-12653-ADB (Lead) and No. 17-cv-10050-ADB (Consol.) (D. Mass.)
- *Impax Laboratories, Inc., v. Zydus Pharmaceuticals Inc & Cadilla Healthcare*, C.A. No. 17-cv-13476 (SRC)(CLW) (D.N.J)

- *Par Pharmaceutical, Inc. et al v. Eagle Pharmaceuticals, Inc.*, C.A. No. 18-cv-00823 (CFC) (D. Del.)
- *Vifor Fresenius Medical Care Renal Pharma Ltd. et al v. Lupin Atlantis Holdings SA et al*, C.A. No. 18-cv-00390 (MN) (D. Del.)
- *Pharmacyclics, et al., v. Cipla, et al.*, C.A. No. 1:18-cv-00192-CFC (Consol.) (D. Del.)
- *Lipocene, Inc. v. Clarus Therapeutics, Inc.*, C.A. No. 1:19-cv-622-WCB (D. Del.)
- *Thorne Labs v Trustees of Dartmouth*, C.A. No. IPR2021-00268 (PTAB).

21. Based on my training, teaching, consulting, and research expertise in the pharmaceutical product development and drug delivery over the last 29 years, I am qualified to serve as an expert witness for this lawsuit.

II. MATERIALS AND OTHER INFORMATION CONSIDERED

22. In forming the opinions expressed in this report, I relied upon my education and experience in the relevant field of the art, and have considered the viewpoint of a person having ordinary skill in the relevant art as of the Priority Date of the ’802 Patent. I have also considered the information provided in the Lemmo report dated June 27, 2022, the Ermakov report dated January 11, 2021, and the Burns report dated January 18, 2021, in addition to the other information and references described and discussed herein.

III. UNDERSTANDING OF LEGAL PRINCIPLES

23. I am not an attorney. For purposes of this report, I have been informed about certain aspects of the law that are relevant to my opinions, as described below.

A. Claim Construction

24. I have been informed that a claim must be construed under the *Phillips* standard. Under that standard, words of a claim are given their plain and ordinary meaning as understood by person of ordinary skill in the art at the time of invention, in light of the specification and prosecution history, unless those sources show an intent to depart from such meaning, as well as pertinent evidence extrinsic to the patent.

25. For purposes of this Opening Report, I applied the plain and ordinary meaning of each term to a person of ordinary skill in art ("POSA") at the time of the alleged invention unless explicitly stated otherwise. I understand that the parties have not yet completed claim construction disclosures and that the Court has not construed any of the claim terms of the ’802 Patent. I reserve the right to amend and/or update my analysis and opinions provided herein to the extent that any party offers a different claim construction and/or to the extent that the Court construes any such claim terms.

B. Infringement

26. I have been informed that for BlueWillow to be liable for direct infringement, it must be shown that BlueWillow has made, used, sold, offered for sale, imported into the United States a product that meets each and every requirement of the claim (either literally or under the doctrine of equivalents).

Based on reports provided by Trutek, I have been informed and understand that Trutek asserts that NanoBio Protect® infringes the asserted claims under a literal infringement theory, and not under the doctrine of equivalents. As such, I have not considered the doctrine of equivalents in my analysis but reserve the right to do so should it be necessary in the future.

27. I have been informed that literal infringement requires that every limitation set forth in a claim must be found in an accused product. I am also informed that direct infringement requires a party to perform each and every step or element of a claimed product or method. I have also been informed that for purposes of any infringement analysis, the comparison is between the properly construed claims and the accused product.

IV. SUMMARY OF OPINIONS

28. For purposes of this report, I have been asked to provide my analysis and opinions concerning the Trutek's assertion that NanoBio Protect® infringes asserted claims 1, 2, 6 and 7 of the '802 Patent. More specifically, I have been asked to provide my analysis and opinions in response to the testing conducted by Dr. Alexei Ermakov and Mr. Shane Burns on behalf of Trutek, as well as the opinions and analysis offered by Dr. Edward Lemmo on behalf of Trutek concerning infringement of the Asserted Claims of the '802 Patent.

29. I reserve the right to respond to any additional opinions or evidence offered by experts on behalf of Trutek concerning the alleged infringement of the Asserted Claims of the ’802 Patent. Further, I reserve the right to supplement this report to address any claim construction positions raised by Trutek and/or in response to any order issued by the Court on claim construction.

30. The opinions set forth in this report are based on my education, knowledge and experience in the area over the past 29 years.

31. In my opinion, NanoBio Protect® does not satisfy each of the elements of claims 1, 2, 6 and 7 of the ’802 Patent, and Trutek and its retained experts have not demonstrated that NanoBio Protect® satisfies each element of claims 1, 2, 6 and 7 of the ’802 Patent.

V. ASSERTED CLAIMS THE ’802 PATENT

32. The Asserted Claims of the ’802 Patent are listed below:

> 1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation where a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:
>
> a) electrostatically attracting the particulate matter to the thin film;
>
> b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

> 2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:
>
> a) electrostatically attracts the particulate matter to the thin film;
>
> b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,
>
> c) inactivates the particulate matter and renders said particulate matter harmless.
>
> 6. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride.
>
> 7. The formulation of claim 2 wherein the at least one cationic agent is Benzalkonium Chloride or Lysine HCL.

VI. PERSON OF ORDINARY SKILL IN THE ART

33. As explained in my Opening Report, I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active workers in the field at the time of the alleged invention, the sophistication of the technology, the type of problems encountered in the art, and the prior art solutions to those problems.

34. In determining the characteristics of a hypothetical person of ordinary skill in the art of the ’802 Patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication

of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the ’802 Patent. Finally, I placed myself back in the relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

35. It is my opinion that the art of the subject matter of the ’802 Patent is a pharmaceutical formulation. Based on the materials I have considered, my own experience, and the knowledge required to design pharmaceutical formulation including the use of excipients, I came to the conclusion that the characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in the art may have worked as part of a multidisciplinary team — including a chemical engineer, microbiologist, or polymer chemist — and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

VII. NANOBIO PROTECT® DOES NOT INFRINGE THE ASSERTED CLAIMS OF THE '802 PATENT

36. For the reasons explained below, it is my opinion that Trutek and its retained experts have not demonstrated that NanoBio Protect® satisfies each element of Asserted Claims 1, 2, 6 and 7 of the '802 Patent.

A. Ermakov and Burns Testing

37. In his report, Dr. Lemmo indicates that he relied on testing conducted by Dr. Ermakov and Mr. Burns, which purportedly demonstrate that NanoBio Protect® and Trutek's NasalGuard products exhibit an electrostatic charge "of the same order of magnitude." I have reviewed the reports prepared by Dr. Ermakov and Mr. Burns and the testing described therein, and disagree with the conclusions reached by Dr. Lemmo on the basis of those reports for the reasons that follow. *E.g.*, Lemmo Report at 3, 9-10.

38. Dr. Ermakov's testing purports to evaluate or measure the amount or magnitude of surface electrostatic charge of NanoBio Protect® and Trutek's NasalGuard after application of the test products to plain sheets of standard printer paper. Similarly, Mr. Burns' testing also purports to evaluate or measure the amount or magnitude of surface electrostatic charge of the test products, but after application to a piece of pig skin, as opposed to printer paper.

39. Based on my experience and knowledge in the relevant field, it is my opinion that there are numerous flaws in how the tests were conducted, the test

results and methods are not indicative of or relevant to how NanoBio Protect® operates when used by individuals and the issue of whether NanoBio Protect® satisfies the elements of the asserted claims, and the test results themselves show significant discrepancies. In addition, there is no evidence that Trutek's NasalGuard products used as controls in the studies meet the limitations of the asserted claims. For each of these reasons, in my opinion, a person of ordinary skill in the art reviewing the Ermakov and Burns testing would not understand the test results to establish that NanoBio Protect® satisfies the claim limitations and/or infringes the asserted claims of the '802 Patent.

40. As an initial matter, both of the Ermakov and Burns tests measure the conductivity of the test formulations, not surface electrostatic charge. I also note that the asserted claims of the '802 patent do not even require a surface charge for the formulation, let alone a particular surface charge or range that would be necessary to achieve result of electrostatically attracting and inhibiting harmful particulate matter from infecting an individual. Moreover, neither of the tests include any calibration standards or any other procedure for validating the methods. Thus, there is extremely limited information, if any, that can be taken from these tests to determine whether NanoBio Protect® or the NasalGuard products used as controls exhibit a surface charge that is sufficient to practice the elements of the asserted claims. For each of these reasons, in my opinion, a person

of ordinary skill in the art would understand that the purported calculations of the surface charge of NanoBio Protect® and NasalGuard alone are meaningless within the context of the claimed invention and do not establish that either product satisfies the elements of the asserted claims.

41. In the Ermakov test, there is no mention of how much of the sample is actually put on the paper before testing. Additionally, the sample was left under ambient conditions where it could be dried or contaminated. None of these considerations were included in the analysis.

42. In addition, neither of the Ermakov or Burns tests were conducted under circumstances that would mimic real life use of NanoBio Protect® in individuals. Both experiments were performed at room temperature, which is significantly lower than body temperature. Similarly, testing the surface charge of NanoBio Protect® as applied on paper and/or a piece of dried pig skin is not indicative or predictive of how the product will operate on human nasal skin or tissue. In this regard, I disagree with Dr. Lemmo's assertion that the "use of pig skin is more predictive than paper regarding how the product would behave on human skin", particularly in view of how Mr. Burns conducted the experiment. As tested, the pig skin was completely dry, which is unlike the typical nasal environment, which has blood supply and is generally very moist. Likewise, the excised portions of pig skin used by Mr. Burns do not accurately replicate *in vivo*

conditions in humans, particularly with respect to different barrier properties, lack of blood vessels, and high variability among skin samples.

43. Finally, in my opinion, the results of the Ermakov and Burns testing are highly variable and as such, would not realistically inform a person of skill in the art as to the nature or magnitude of any surface charge exhibited by NanoBio Protect®.

44. For example, with respect to the Ermakov testing, I note that paper is not conductive, but it does have a charge. The paper has an average surface charge of 6.67×10^{-15} Coloumbs per sq. inches and the NanoBio Protect® solution has a surface charge of 4.35×10^{-14} Coloumbs per sq. inches. Both of Trutek's products NasalGuard Airborne Blocker and NasalGuard Misting Spray gave significantly higher charge values of 8.32×10^{-14} Coloumbs per sq. inches and 7.19×10^{-14} Coloumbs per sq. inches than the NanoBio product.

45. With respect to the Burns testing, I note that while the 3 experiments conducted with Trutek's NasalGuard gave fairly similar results (0.24 nC, 0.27 nC, 0.24 nC for an average of 0.25 nC), the 3 experiments conducted with NanoBio Protect® gave an extremely wide range of results (0.85 nC, 0.09 nC, 0.35 nC for an average of 0.43 nC). The high variability in these results suggest to a person of skill in the art that the experiment was flawed and unreliable.

46. Moreover, the results between the Ermakov and Burns experiments are inconsistent. More specifically, Burns reports that NanoBio Protect® exhibits a higher charge per square centimeter (0.006 nC/cm^2) than NasalGuard (0.003 nC/cm^2). However, Ermakov reports the opposite result, with NasalGuard (8.32x 10^{-14} and 7.19 $x10^{14}$ Coloumbs per sq. inches) exhibiting a higher charge per square inch than NanoBio Protect® (4.35x 10^{-14} Coloumbs per sq. inches).

47. The inconsistency in the experimental results is even more extreme when taking into account Mr. Burns' prior testing of the NasalGuard product. In prior experiments applying the same test procedure using pig skin, Mr. Burns reported a charge per square centimeter of 0.146 for nC/cm^2 for Trutek's Nasal Guard. Exhibit 2 (July 30, 2019 Technical Report prepared by Shane Burns at page 5 (reporting surface charge measurements of NasalGuard)). This is an almost 100-fold difference from the NasalGuard results Mr. Burns obtained and reported in his January 18, 2021 report comparing NasalGuard with NanoBio Protect®.

B. NanoBio Protect® Does Not Satisfy Each Element of the Asserted Claims of the '802 Patent

48. Additionally, I disagree with the overall "findings and conclusions" listed by Dr. Lemmo at pages 1-3 of his report and his ultimate opinions that NanoBio Protect® satisfies each of the elements of asserted claims 1, 2, 6 and 7 of the '802 Patent.

49. Independent claim 1 recites a method for "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein a "formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and "electrostatically attracting the particulate matter to the thin film." It is my understanding that each of these claim elements must necessarily occur during use of the accused product to demonstrate infringement.

50. Independent claim 2 is similar in that it recites a formulation for "electrostatically inhibiting harmful particulate matter from infecting an individual" wherein a "formulation is applied to skin or tissue of nasal passages of the individual in a thin film" and once applied, the formulation "electrostatically attracts the particulate matter to the thin film." Likewise, it is also my understanding that the accused product must necessarily perform or exhibit each of these claim elements to demonstrate infringement.

51. Asserted claims 6 and 7 are dependent claims that depend from claim 2. As such, it is my understanding that each of the elements of claim 2 must also be met in order to demonstrate infringement of claims 6 and 7 of the '802 Patent.

52. Even if a person of skill in the art were to accept the results of the Ermakov and Burns testing as demonstrating that NanoBio Protect® exhibits an electrostatic charge when "applied to skin or tissue of nasal passages" of an individual (a point which I dispute for the reasons explained above), the Ermakov

and Burns testing does not demonstrate that the purported electrostatic charge operates to "inhibit[] harmful particulate matter from infecting an individual" or "electrostatically attracts the particulate matter to the thin film." More specifically, the Ermakov and Burns testing bears no relation to whether the purported electrostatic charge exhibited by NanoBio Protect® actually operates to: (1) inhibit infection in an individual, or (2) is sufficient to electrostatically attract particulate matter to the thin film, or (3) the thin film creates an impermeable barrier. This is particularly true given that the Ermakov and Burns testing was conducted on a piece of paper and dried pig skin, neither of which are representative or predictive of what would occur in the nasal passages of an individual.

53. I also disagree with Dr. Lemmo's assertion that "germs are 'bound' to the nano-droplets" of NanoBio Protect®. Lemmo Report at 11. Dr. Lemmo does not provide a citation for this specific assertion, but does reference a portion of BlueWillow's website elsewhere in his report. In reaching his opinion that "germs are 'bound' to the nano-droplets" of NanoBio Protect®, Dr. Lemmo appears to mischaracterize BlueWillow's website. The portion of the website cited by Dr. Lemmo states: "And lastly, when bound to nano droplets, BZK is non-irritating to the skin." Lemmo Report at 10; Exhibit D. This statement clearly refers to BZK being "bound" to the nano droplets, and not any "germs." Dr. Lemmo cites no other materials or information concerning what may or may not

be "bound" to the NanoBio Protect® nano droplets, apart from the citation above indicating that BZK (and not germs) is bound to the nano droplets.

54. I also disagree with Dr. Lemmo's assertion that when administered, NanoBio Protect® "forms a thin film that adheres to the skin or tissue of nasal passages." Notably, Dr. Lemmo does not rely on any test results to demonstrate that this element of the asserted claims is met by NanoBio Protect®. Instead, Dr. Lemmo makes the unsupported assertion that "[i]f that were not the case, the liquid would instantly drip out of the user's nose," noting that BlueWillow's website indicates that "the droplets persist on the skin for four or more hours." Lemmo Report at 11. Nowhere does the material cited indicate that when applied, NanoBio Protect® forms a thin film on the nasal passages, let alone a thin film that persists for hour hours or operates to electrostatically attract and inhibit particulate matter from infecting an individual by creating a permeability barrier.

55. In this regard, I note that Exhibit E to Dr. Lemmo's report (excerpt from BlueWillow website) indicates that "NanoBio Protect's nanodroplets are small enough to reach germs that hide in the deep layers of skin, but big enough to prevent absorption through the skin into the bloodstream." As such, a person of ordinary skill in the art would understand that the size of the NanoBio Protect® nanoemulsion facilitates penetration into the deep layers of the skin (hair follicles,

sebaceous glands, sweat glands, etc.) and does not work by forming a thin, impermeable barrier on the surface of the skin in and around the nasal passages.

56. Finally, I also disagree with Dr. Lemmo's assertion that NanoBio Protect® satisfies the claim element of "holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film."

57. In support of his opinion, Dr. Lemmo appears to again rely on the results of the Ermakov and Burns testing that purport to demonstrate that NanoBio Protect® exhibits an electrostatic charge, concluding that based on this purported electrostatic charge, the NanoBio Protect® nano droplets necessarily electrostatically attract particulate matter (e.g., germs), holding them in place. As explained above, the Ermakov and Burns testing does not demonstrate that NanoBio Protect® operates in this manner.

58. In addition, Dr. Lemmo does not address the claim element that requires "adjusting the adhesion of the thin film" other than to assert that the "product forms a thin film that adheres to the skin or tissue of his nasal passages," a point I dispute as explained above. Nor does Dr. Lemmo address the claim element that requires "adjusting the cohesion of the formulation to provide adequate impermeability to the thin film" other than by asserting that the "droplets

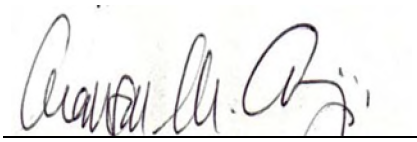
significantly hydrate skin to avoid dryness or cracking that can allow germs in." A person of ordinary skill in the art would understand that a formulation such as NanoBio Protect®, which purports to alleviate dryness in the nasal passage, does not necessarily do so as a result of any "adjustment" in the "cohesion of the formulation" or by existing as an impermeable thin film on the nasal passages.

VIII. CONCLUSION

59. For the aforementioned reasons, in my opinion, NanoBio Protect does meet every element of claims 1, 2, 6 and 7 of the '802 Patent and therefore, does not infringe the Asserted Claims of the '802 Patent.

Date: August 15, 2022

Respectfully submitted,



Mansoor M. Amiji, Ph.D.

CERTIFICATE OF SERVICE

I hereby certify that on **August 15, 2022**, I caused the foregoing document to be served via email and First Class Mail on:

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Alan J. Gocha

EXHIBIT 3

[redacted]

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

REPLY EXPERT REPORT OF MANSOOR M. AMIJI, PH.D. ON INVALIDITY

[redacted]

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[redacted]

I, Dr. Mansoor M. Amiji, submit this Reply Report as follows:

1. I have been retained as an expert witness on behalf of BlueWillow Biologics, Inc. ("BlueWillow") for the above-captioned district court patent litigation case, with case number 2:21-cv-10312-SJM-RSW. I am being compensated for my time in connection with this litigation at my standard consulting rate of $900 per hour. My compensation is not affected by the outcome of this matter.

2. I have been informed that Trutek has accused BlueWillow of infringing claims 1, 2, 6 and 7 of U.S. Patent No. 8,163,802 ("the '802 Patent") and have been asked to provide my opinions regarding whether those claims of the '802 Patent are invalid.

3. I have reviewed the two reports served by Trutek, prepared by Dr. Edward Lemmo and Mr. Amirali Haidri, and have been asked to prove my further opinions and analysis as to the opinions expressed in those reports. Based on my review and analysis, nothing in the Dr. Lemmo's report or Mr. Haidri's report changes my analysis and opinions that claims 1, 2, 6 and 7 of the '802 Patent are invalid for the reasons described herein, as well as for the reasons described in my Opening Expert Report on Invalidity (dated June 27, 2022) and my Declaration in Support of BlueWillow's Claim Construction Brief (dated September 8, 2022).

[redacted]

4. My analysis and opinions provided herein are limited to claims 1, 2, 6 and 7 of the ’802 Patent, and I reserve the right to amend and/or update my analysis and opinions should Trutek assert additional claims in this litigation.

5. This report sets forth the opinions that I have formed based on the information available to me as of the date below. The opinions and fact set forth in this report are based upon information and my analysis of the asserted patent, the prior art, the state of the art at the time of the invention, as well as my knowledge and experience in the relevant field. It is my understanding that expert discovery is ongoing. I reserve the right to supplement or amend this report based on additional information made available to me, including in light of any expert reports or other responses to the subject matter addressed herein.

6. I expect to be called to testify at trial in the above-captioned action. If called upon, I am prepared to testify about my background, qualifications, and experience, as well as about the issues set forth in this report. If I am called upon to testify at trial, I may rely on exhibits and/or visual aids to demonstrate the bases for my opinions. I have not yet prepared any such exhibits or visual aids. I also reserve the right to provide a tutorial relating to the general topics contained in this report.

7. I am not currently and have not at any time in the past been an employee of BlueWillow. I have no financial interest in BlueWillow.

[redacted]

I. MATERIALS AND OTHER INFORMATION CONSIDERED

8. In forming the opinions expressed in this report, I relied upon my education and experience in the relevant field of the art, and have considered the viewpoint of a person having ordinary skill in the relevant art as of the Priority Date of the ’802 Patent.

9. I have considered the materials referenced herein, including the ’802 Patent, the file history of the ’802 Patent, in addition to the referenced in my Opening Expert Report on Invalidity (dated June 27, 2022) and my Declaration in Support of BlueWillow’s Claim Construction Brief (dated September 8, 2022).

II. UNDERSTANDING OF PATENT LAW

10. I am not an attorney. For purposes of this report, I have been informed about certain aspects of the law that are relevant to my opinions, as described in my Opening Expert Report on Invalidity (dated June 27, 2022) and my Declaration in Support of BlueWillow’s Claim Construction Brief (dated September 8, 2022).

III. SUMMARY OF OPINIONS

11. For purposes of this report, I have been asked to provide my analysis and opinions concerning the invalidity of asserted claims 1, 2, 6 and 7 of the ’802 Patent. I reserve the right to respond to any opinions or evidence offered by experts on behalf of Trutek concerning the invalidity of the claims of the ’802 Patent. Further, I reserve the right to supplement this report to address any claim

[redacted]

construction positions raised by Trutek and/or in response to any order issued by the Court on claim construction.

12. The opinions set forth in this report are based on my education, knowledge and experience in the area over the past 29 years.

13. In my opinion, claims 1, 2, 6 and 7 of the ’802 Patent are invalid as anticipated and/or are obvious in view of the prior art described herein under 35 U.S.C. §§ 102 and 103.

14. It is also my opinion that claims 1, 2, 6 and 7 of the ’802 Patent are not directed to patent-eligible subject matter under 35 U.S.C. § 101.

15. Finally, it is also my opinion that claims 1, 2, 6 and 7 of the ’802 Patent do not satisfy the definiteness, utility, written description and/or enablement requirements of 35 U.S.C. § 112.

IV. THE PERSON OF ORDINARY SKILL IN THE ART

16. The ’802 Patent issued from U.S. App. No. 12/467,271 (the “’271 application”), which in turn was filed on May 16, 2009. The patent claims priority to provisional application No. 61/078,478, which was filed on July 7, 2008. For purposes of this Opening Report only, I assume that the ‘802 Patent is entitled to the July 7, 2008 priority date.

17. I understand that there are multiple factors relevant to determining the level of ordinary skill in the pertinent art, including the educational level of active

[redacted]

workers in the field at the time of the alleged invention, the sophistication of the technology, the type of problems encountered in the art, and the prior art solutions to those problems.

18. In determining the characteristics of a hypothetical person of ordinary skill in the art of the ’802 Patent at the time of the claimed invention, I considered several things, including the type of problems encountered in this field, and the rapidity with which innovations were made. I also considered the sophistication of the technology involved, and the educational background and experience of those actively working in the field, and the level of education that would be necessary to understand the ’802 Patent. Finally, I placed myself back in the relevant period of time and considered the state of the art and the level of skill of the persons working in this field at that time.

19. As stated in my Opening Report, it is my opinion that the art of the subject matter of the ’802 Patent is a pharmaceutical formulation. Based on the materials I have considered, my own experience, and the knowledge required to design pharmaceutical formulation including the use of excipients, I came to the conclusion that the characteristics of a person of ordinary skill in the art of the ’802 Patent would be someone who had at least an M.S. degree in chemical engineering, pharmaceutical sciences, or a related field (or the equivalent) with several years of experience with pharmaceutical formulation. Also, a person of ordinary skill in

[redacted]

the art may have worked as part of a multidisciplinary team— including a chemical engineer, microbiologist, or polymer chemist—and drawn upon not only his or her own skills, but also taken advantage of certain specialized skills of others on the team, *e.g.*, to solve a given problem.

20. I understand that Trutek's experts disagree with my opinion regarding the level of a person of ordinary skill in the art as it applies to the subject matter of the '802 Patent. More specifically, I understand Trutek's experts to opine that the person of ordinary skill in the art would have a much lower level of skill, and "should be able to create the formulations described in the patent" but "need not possess an advanced degree. Further, he does not even need to possess an undergraduate degree. He must be a technician with several years of experience as a formulator. The key requirement is his acquired experience necessary to create a wide variety of formulations from the class of ingredients disclosed in the '802 Patent."

21. I disagree with the positions taken by Trutek's experts on the level of ordinary skill in the art of the '802 Patent. In my opinion, it is not enough to simply possess undetermined years of experience in creating "a wide variety of formulations from the class of ingredients disclosed in the '802 Patent" and the ability to read the patent and make the various formulations described in the patent.

[redacted]

22. The claimed invention of the ’802 Patent is not directed merely to making and using the various formulations described in the ’802 Patent specification, but rather, specific formulations that are capable of “electrostatically inhibiting harmful particulate matter from infecting an individual” wherein the “formulation is applied to skin or tissue of nasal passages of the individual in a thin film” and “electrostatically attracting the particulate matter to the thin film.” ’802 Patent, Claim 1. The claimed invention also requires the particular formulation to be applied in a “thin film,” which in turn provides sufficient adhesion to the skin and sufficient cohesion “to provide adequate impermeability to the thin film.” Notably, the ’802 Patent does not provide any information on the specific thickness of film, which ingredients and formulation properties provide adhesion to the skin and for how long, as well as any data or test results demonstrating that any of the formulations disclosed therein provide or achieve any of these properties of the claimed invention. Nor does the ’802 Patent even identify any tests or methods that a person of skill in the art could use to test a subject formulation for these properties.

23. Without the disclosure of this information, a person who simply possesses the ability to create a formulation from a list of ingredients would have no way of knowing if any particular formulation falls within the scope of the claims from the information provided in the patent, and certainly would not have any

[redacted]

experience and knowledge of how to make this assessment, according to the standard set forth by Trutek's experts. Likewise, a person who simply possesses the experience and ability to read the '802 Patent and make certain formulations from the ingredients listed in the '802 Patent would not have the requisite level of skill to assess whether any such formulations are sufficient to actually achieve the result described in the asserted claims, including "electrostatically attracting," "electrostatically inhibiting harmful particulate matter from infecting an individual," or providing adequate adhesion, cohesion, or impermeability of the thin film upon application of the formulation to a person's skin.

V. CLAIMS 1, 2, 6 AND 7 OF THE '802 PATENT ARE INVALID

24. As an initial matter, I note that I am providing technical opinions based on my review of the '802 Patent and my knowledge and experience in the relevant field. While I am not a lawyer, I have been informed of the relevant legal standards as explained above and in my earlier reports. I have used these legal standards to guide my technical analysis and opinions contained in each of my expert reports, which are being provided from the perspective of a person of ordinary skill in the art to which the claimed invention is directed. My opinions expressed in this matter are limited accordingly and as such, I have not been asked to respond to or provide any opinions as to the legal and/or commercial arguments contained in Dr. Lemmo's and Mr. Haidri's responsive expert reports.

[redacted]

25. In addition, Dr. Lemmo and Mr. Haidri provide only limited critiques of certain prior art discussed in my opening report. With respect to the prior art specifically addressed by Trutek's experts, I disagree with their analysis for the reasons provided below.

26. In summary, I have reviewed Dr. Lemmo's Report and Mr. Haidri's Report, and none of the opinions or analysis therein changes my opinion that each of the asserted claims of the '802 Patent are invalid for the reasons described in my Opening Report and Claim Construction Declaration.

A. Response to Lemmo Report

27. In addition to Dr. Lemmo's (and Mr. Haidri's) opinion regarding the level of ordinary skill in the art, which I have addressed above, Dr. Lemmo also offers opinions related to the purported "Hold" function of the '802 Patent, the disclosure of the Rolf patent application, and the purported "commercial success" of the claimed invention. I disagree with Dr. Lemmo's analysis on all of these points. I also note that Dr. Lemmo has not provided any technical expert opinion or analysis as to whether a person of ordinary skill in the art reading the '802 patent would: (1) understand whether the claimed invention to be directed to patent eligible subject matter or a natural phenomenon, (2) credibly believe the claimed invention to work in the manner described and claimed; (3) be able to make and use the claimed invention without undue experimentation; or (4) understand from

[redacted]

reading the specification that the inventor was in possession of the claimed invention.

28. First, Dr. Lemmo asserts that "holding is a critical aspect of the patent claims since the power of the electrostatic forces to attract airborne particles ***must be enhanced using the principles of adhesion and cohesion***. This interaction of the formulation with foreign particles found in the air, by electrostatically attracting and capturing them and then holding them in place, sets up the opportunity for the formulation's ingredients to inactivate them prior to entry into the respiratory system." (emphasis added). Dr. Lemmo also explains that "[h]olding is a protective concept based on adhesive and cohesive properties," and "the mechanism of the formulation to carry out the protection it claims to afford the user would be incomplete if the formulation did not have the adhesive and cohesive properties required to hold the particles in place." Likewise, he explains that the "[a]ttraction by electrostatic forces is enhanced by the holding properties of adhesion and cohesion" and it is these properties that "set up the formulation's biocidic ingredients to inactivate and kill bioactive particles."

29. In other words, Dr. Lemmo appears to takes the position that the concepts of "holding" by "adhesion" and "cohesion" are a critical aspect of the claimed invention. I note, however, that Dr. Lemmo's explanation is not supported by the specification of the '802 patent. For example, the terms "adhesion" and

[redacted]

"cohesion" appear only in the '802 patent claims. The specification is completely silent as to these principles and their purported impact on the asserted "holding" mechanism of action described by Dr. Lemmo. Likewise, while the '802 patent specification describes a laundry list of potential ingredients and formulations, the patent provides no information as to the "adhesive" and "cohesive" properties of any of the formulations, or how one of skill in the art could assess those properties to determine whether they provide the purported "enhanced holding" function he describes.

30. In addition, while the '802 patent specification references the purported "holding" feature of the claimed invention, it does so in the context of electrostatic attraction and not with respect to any "adhesive" or "cohesive" properties of the formulation. For example, the "Field of the Invention" describes "these electrostatically charged nasal application products capture and hold the contaminants." '802 Patent at 2:3-4. The "Summary of the Invention" is consistent, describing the invention as "creating an electrostatic field in an area near about the nasal passages. . . . these electrostatically charged nasal application products are used to hold the contaminants including microorganisms, viruses, bacterial, and other harmful or toxic particulate outside the body and render them harmless." '802 Patent at 3:46-52. Consistent with that discussion, the '802 patent describes using formulations with "at least one polyquaternary ammonium

[redacted]

compound" which is "capable of creating an electrostatic field on and around a surface." '802 Patent at 4:39-42. Notably, this section of the patent does not describe or reference the need for any particular adhesive or cohesive properties of the formulation or ingredients therein. Thus, in my opinion, a person of ordinary skill in the art reading the '802 Patent would not understand the specification to describe or disclose the claimed invention in the manner suggested by Dr. Lemmo.

31. Second, another inconsistency raised by Dr. Lemmo relates to his discussion of the claimed "cationic" and "biocidic" agents. Dr. Lemmo refers to the "cationic agent" as one that attracts the bioactive particles, and explains that the formulation "also contains a biocidic agent that acts to destroy or neutralize the captured bioactive particles." Lemmo Report at 8. Dr. Lemmo's description makes its appear as though these are two separate concepts. They are not. In particular, agents that are cationic are also biocidic by their nature. This is particularly relevant as to the prior art Wahi patents, whereby the compounds and compositions described therein have both properties as well. In my opinion, Dr. Lemmo's suggestion that there is a separate "holding" function and then a different agent or compound separately comes in to kill or deactivate the harmful matter is inconsistent with the basic nature of these compounds.

32. Third, Dr. Lemmo also presents a discussion of the Rolf patent application, which I disagree with for the reasons below. I also note that Dr.

[redacted]

Lemmo offers no other critique or analysis of any of the other prior art references I relied on in my opening report in the course of forming my opinions.

33. With respect to Rolf, Dr. Lemmo notes that the application is directed to essential oils, which are geared toward aromatherapy, perfumes, and air fresheners, rather than deactivating harmful particulate matter. However, Dr. Lemmo fails to consider the composition of these essential oils, i.e., that they are cationic agents. Given their cationic nature, they will inherently function to provide an electrostatic charge, in addition to holding and deactivating particulate matter, even if that aspect is not expressly stated in Rolf.

34. Dr. Lemmo also asserts, without providing any citation in support, that "[r]eports in the literature suggest essential oils have skin irritating properties when applied, and others suggest more severe toxicity profiles, putting the user at risk for more serious medical problems." Lemmo Report at 10. In my opinion, Dr. Lemmo oversimplifies this concept. Essential oils have a wide variety of uses, and specific amounts that can be applied, making it difficult to generalize any such toxicity issues or skin irritation concerns. Indeed, Rolf clearly provides evidence of applying formulations containing essential oils, and their cationic and biocidic properties would be well understood by one of ordinary skill in the art.

35. I also disagree with Dr. Lemmo's final assertion that "the patch would not function as described by Rolf." Lemmo Report at 11. As I understand Dr.

[redacted]

Lemmo's opinion, he focuses on the fact that the "only adhesive property of Rolf's patch is its ability to adhere to the skin" and that the "side of the patch facing the airborne particles has no adhesive properties." A person of ordinary skill in the art reading the Rolf patent application would understand that the patch described in Rolf would operate according to the same principle as the claimed invention. More specifically, because the Rolf patch acts like a sponge, attracting the harmful particulate matter to the inside of the patch, it is irrelevant that the outside of the patch is not adhesive. The cationic nature of the Rolf patch composition has the same attractive, holding, and biocidic properties as taught by the '802 patent. In other words, the Rolf patch prevents particulate matter from entering the nose through a physical mechanism by attracting the matter and employing an agent that inactivates the matter.

36. Finally, I disagree with Dr. Lemmo's final opinion contained in his report that the alleged commercial success of Trutek's products "is due solely to the performance and features of the claimed invention of the '802 Patent." I have been informed that while the commercial success of a patented product may be relevant to the non-obviousness of the claimed invention, there must be a nexus or a connection between the claimed invention and the sales of the product.

37. For the same reasons provided in my Responsive Report on non-infringement, it is my opinion that Trutek and its experts have not presented any

[redacted]

evidence that Trutek's NasalGuard products actually practice every element of the '802 patent claims. More specifically, while the testing that Dr. Lemmo relied on (the Burns and Ermakov testing) purports to show that the NasalGuard products exhibit an electrostatic charge, those test results are meaningless to a person of ordinary skill in the art within the context of the claimed invention and do not establish that the Nasal Guard products practice each element of the '802 patent claims.

38. The test results do not demonstrate that the purported electrostatic charge of NasalGuard operates to "inhibit[] harmful particulate matter from infecting an individual" or "electrostatically attracts the particulate matter to the thin film." In addition, the testing bears no relation to whether the purported electrostatic charge exhibited by NasalGuard (1) operates to inhibit infection in an individual or (2) is sufficient to electrostatically attract particulate matter to the thin film. Likewise, Dr. Lemmo and Trutek's experts have provided no evidence or test results demonstrating that any thin film created upon application of the NasalGuard products (or NanoBio Protect) creates an impermeable barrier or operates according to the "holding" by "adhesion" and "cohesion" theory advanced by Dr. Lemmo in his responsive report.

[redacted]

B. Response to Haidri Report

39. Based on my review, much of the Haidri Report appears to be legal argument. As noted above, I am not a legal expert. Rather, my opinions are technical in nature and from the perspective of a person of ordinary skill in the art with respect to the subject matter disclosed and claimed in the '802 Patent. Nevertheless, there are some issues raised by Mr. Haidri in his report that I disagree with from a technical perspective, based on my knowledge and experience in the relevant field.

40. For example, on pages 29 and 30 of his Report, Mr. Haidri lists the five "Objects of the Invention" as stated in the '802 Patent, and then states that "all of the formulations listed in the tables will function to achieve the five objectives and will act as recited in the claims." He repeats this assertion throughout his report. I disagree. As explained in my Opening Report, a person of ordinary skill in the art reading the '802 Patent specification would not understand that all of the formulations, with the varying ranges disclosed, would necessarily function as described according to the "Objects of the Invention" or in the manner claimed in the '802 Patent.

41. While the '802 Patent does provide a laundry list of different ingredients and varying ranges of those ingredients as potential formulations, the '802 Patent does not contain any disclosure that would reasonably inform a person

[redacted]

of skill in the art that the listed formulations in fact operate in this manner. In pharmaceutical compositions with the requisite properties, it is important to provide the exact amount and type of ingredients to be used, process of preparation, and quality control tests that show that the product achieves its intended goal. In this regard, it is important to note that the '802 patent claims do not merely recite a particular formulation containing certain categories of ingredients. Rather, the '802 patent claims require the formulation to "electrostatically inhibit harmful particulate matter from infecting an individual, whereby the formulation (1) "electrostatically attracts the particulate matter to the thin film," (2) "holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film," and (3) "inactivates the particulate matter and renders said particulate matter harmless."

42. The '802 Patent does not provide any test results for even a single formulation demonstrating that it would perform each of these functions as claimed. In view of the wide ranges of ingredients and amounts included in the ten tables of listed formulations and the lack of any data supporting that even one of the formulations operates in this manner, a person of ordinary skill in the art reading the '802 patent would not credibly believe the conclusory and unsupported statement in the '802 patent that "[a]ll of the formulations described in TABLE 1-

[redacted]

10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein," particularly in view of the recognition that varying these percentages can affect the potency and consistency of the formulation. '802 Patent at 10:8-15.

43. On page 37 of his report, Mr. Haidri refers to Trutek's NasalGuard products and states that all of the products sold by Trutek "are based upon the specification and claims of the '802 Patent." Mr. Haidri provides no explanation or basis for his conclusion that the NasalGuard products satisfy the claims of the '802 Patent. Additionally, there is no clinical evidence cited anywhere in Mr. Haidri's report that shows Trutek's NasalGuard to function or operate according to the '802 patent claims. For the same reasons as explained above and in my Responsive Report, in my opinion, the testing and analysis provided by Trutek and its experts purportedly demonstrating that the NanoBio Protect and NasalGuard products exhibit a surface electrostatic charge is scientifically flawed, not indicative of or relevant to how the products operate when used by individuals, and does not demonstrate that the products practice each element of the '802 patent claims.

44. With respect to credible utility, lack of enablement and written description, I disagree with Mr. Haidri's opinion that claims 1, 2, 6 and 7 of the '802 Patent "describe a use that is beneficial to the public, and the specification

[redacted]

and claims provide information that a person of ordinary skill would employ to make and use the formulations described therein without undue experimentation." Haidri Report at 44. Mr. Haidri describes that "beneficial" use as "inhibiting harmful particulate matter from infecting an individual through nasal inhalation." For the reasons provided earlier, while I agree in the abstract that this general statement of use would be beneficial, in my opinion, a person of skill in the art reading the '802 patent claims and specification would not understand that to be a complete description of the claimed invention. Nor would a person of skill in the art reading the '802 patent claims and specification credibly believe that the claimed invention operates in the manner claimed, e.g., by "electrostatically inhibiting" harmful particulate matter.

45. I also disagree with the rest of Mr. Haidri's statement that "the specification and claims provide information that a person of ordinary skill would employ to make and use the formulations described therein without undue experimentation." Haidri Report at 44 (emphasis added). Again, I believe that Mr. Haidri is incorrectly characterizing the claimed invention. The claimed invention is not merely the list of formulations described in the patent. Rather, the claimed invention is directed to a formulation, or a method of using that formulation, that performs each of the specific functions recited in the claims. For the reasons I have already provided, in my opinion, the '802 patent specification

[redacted]

does not teach a person skilled in the art how to make the claimed invention without undue experimentation.

46. Likewise, I disagree with Mr. Haidri's statement that each of the ten embodiments listed in the '802 Patent "is a formulation that has been shown to work." Haidri Report at 46 and 51. The '802 Patent does not teach or disclose to a person skilled in the art which combinations or percentages of the different components are necessary to provide the claimed functionality. Nor does the '802 Patent provide any examples with test results of any of the disclosed formulations, or any guidance to the person skilled in the art as to what types of tests should be conducted to determine whether a particular formulation operates to provide the claimed functionality.

47. With respect to Wahi '488 and '481, I disagree with Mr. Haidri that these patents do not teach application to nasal passages, holding the particulate matter in place, or inactivating or killing the particulate matter. For example, Wahi '488 discloses "creating an electrostatic field in an area near a human *nasal passage*" that "may either repel or *attract airborne contaminants* or both, *to prevent such contaminants from entering the nasal passage* and body of a user." Wahi '488 at Abstract. Further, Wahi '488 "is primarily directed to the prevention of harmful effects caused by airborne contaminants which enter the human nasal passage during breathing." Wahi '488 at 2:62-64. Additionally, Wahi '488

[redacted]

discloses a formulation that contains "one or more electrostatic materials," among other ingredients such as a carrier and an adhesive, which "is applied at or near the nasal passage." Wahi '488 at Abstract; 6:46-66; 6:4-7. With respect to holding the particulate matter in place, Wahi '488 expressly discloses that that the airborne contaminants are "attracted to and adhere to" the product. Wahi '488 at 7:19-25. Finally, Wahi '488 also discloses preventing harmful effects caused by airborne contaminants such as viruses, germs, bacteria and fungi. A person of ordinary skill in the art that killing such organisms is a means of preventing their harmful effects. I also disagree with Mr. Haidri's analysis of Rolf as combined with Wahi '488 and '481, for the same reasons provided above in connection with my analysis of Dr. Lemmo's opinions.

48. I also disagree with Mr. Haidri's analysis of Wadstrom, both alone and in combination with Rolf, and more specifically, his assertion that Wadstrom does not disclose holding the particulate matter in place, or inactivating or killing the particulate matter. For example, Wadstrom discloses "a nasal spray . . . for capturing . . . airborne . . . microorganisms, as well as . . . airborne . . . viruses in the nasal cavity." Wadstrom at [0006]. Wadstrom observes that, because "all microbes and viruses are negatively charged," this "principle may be used to trap airborne and/or liquid borne allergens." Wadstrom at [0004], [0020]. In addition, Wadstrom discloses a "product for . . .absorption of airborne . . . microbes as well

[redacted]

as viruses, and microbial antigens" that "binds" the contaminants using a "positively charged entity," which attracts negatively charged contaminants to the product. Wadstrom at [0001], [0004], [0020]. In this regard, Wadstrom also teaches that its claimed formula "efficiently bound" at least two different types of bacteria. Wadstrom at [0031]. In addition, Mr. Haidri's description of the purported "CATCH," "HOLD," and "KILL" aspects of the invention as three separate functions performed by three separate ingredients is inconsistent with the nature of those ingredients. A cationic polyquaternary ammonium biocide (e.g., QUAB 342 (3-chloro-2-hydroxypropyl-dimethyl-dodecyl-ammonium chloride) as disclosed in Wadstrom) performs all three functions. Finally, Wadstrom further discloses using members of a "quaternary ammonium group" (QAC) to create the requisite positive charge. Wadstrom at [0009]. As explained previously, sufficient quantities of QACs have not only cationic properties but also can kill contaminants.

49. Finally, I also disagree with Mr. Haidri's analysis of the Baker patents and applications (Baker '189 and Baker '476), both alone, and in combination with the other references discussed in my Opening Report. As an initial matter, I disagree with the assertion that Baker '189 and Baker '476 do not disclose holding the particulate matter in place by adjusting the adhesion and cohesion. In particular, Mr. Haidri states that Baker '189 "teaches the CATCH and KILL

[redacted]

elements. However, it is silent regarding the HOLD element" and "there is no mention of adjusting the adhesion and cohesion of the nanoemulsion to achieve adequate impermeability"). Haidri Report at 66 (repeating the same for Baker '476 at page 68). Again, these functions are not performed by three separate ingredients. Benzalkonium chloride as disclosed in Baker '476 imparts positive charge that can "CATCH," "HOLD," and "KILL."

50. In this regard, I note the relationship between the research conducted by Dr. Baker at the University of Michigan and the technology used by BlueWillow in NanoBio Protect. It is my understanding that the work is related, and that BlueWillow licensed and used the technology described in the Baker patents and applications in the course of developing NanoBio Protect. Indeed, the Baker patents and applications disclose the formulation and composition of NanoBio Protect.

51. [redacted]

[redacted]

TABLE 5

NE-1 formulations with 0.13% BZK.

Formulation Excipients	NE-1 (Surfactant Blend Ratio: 1:2)	NE-1 (Surfactant Blend Ratio: 1:5)	NE-1 (Surfactant Blend Ratio: 1:9)	NE-1 (Surfactant Blend Ratio: 1:14)	NE-1 (Surfactant Blend Ratio: 1:18)	NE-1 (Surfactant Blend Ratio: 1:27)
Purified Water	95.744	91.805	83.929	76.047	68.2	58.458
BZK	0.13	0.13	0.13	0.13	0.13	0.13
Poloxamer 407	0.296	0.592	1.184	1.776	2.368	3.552
Glycerol	0.504	1.008	2.016	3.024	4.032	6.048
Soybean Oil	3.139	6.279	12.558	18.837	25.116	37.674
EDTA	0.186	0.186	0.186	0.186	0.186	0.186
Total	100%	100%	100%	100%	100%	100%

52. Looking at Baker ’476 for example, it discloses an embodiment in paragraph [0232]:

> Thus, in some embodiments, the present invention provides antimicrobial oil-in-water nanoemulsions having one or more of a first component comprising a solvent (e.g., ethanol, glycerol, polyethylene glycol, isopropanol), a second component comprising a halogen-containing compound (e.g., benzethonium chloride, methylbenzethonium chloride, N-alkyldimethylbenzylammonium chloride), alkyldimethyl 3,4-dichlorobenzyl ammonium chloride, cetypyridinium chloride), a third component comprising a surfactant (e.g., TWEEN-20, TRITON X-100, SDS, Poloxamer, sodium lauryl Sulfate), and a fourth component (e.g., an addition Surfactant, methanol, EDTA, tribuyl phosphate, tyloxapol, 2-phenylphenol, Sodium chloride, trisodium citrate hyhydrate, citric acid, sodium fluoride, peppermint extract, NaOH, L-alanine, inosine, ammonium chloride, PBS, menthol, thymol, eucalyptol, methyl salicylate, triclosan, gycerin, natrosol, benzoyl peroxide, Salicyclic acid, citrate buffer, sodium saccharin, tergitol, monoethanolamine, hypertonic saline Solution, calcium chloride, hydrogen peroxide, polyamer 407).

The disclosure of this embodiment in Baker ’476 [redacted]

[redacted]

[redacted]

53. In addition, Baker ’476 specifically discloses the use of quaternary ammonium compounds, including benzalkonium chloride (BZK), in the non-toxic nanoemulsions of the invention (’476 patent at [0159]) as well as specific embodiments incorporating BZK (’476 patent at [0142]).

54. Baker ’476 also describes two other specific oil-in-water nanoemulsion embodiments – W_{80}5EC and W_{20}5EC – [redacted] More specifically, paragraph [0137] of Baker ’476 describes the formulation of W_{80}5EC:

> In alternative embodiments of the present invention, the formulations comprise from about 5 vol. % of TWEEN 80, from about 8 vol. % of ethanol, from about 1 vol. % of CPC, about 64 vol. % of oil (e.g., soybean oil), and about 22 vol. % of DiH_2O (designated herein as W_{80}5EC).

Paragraph [0138] describes the formulation of W_{20}5EC:

> In still other embodiments of the present invention, the formulations comprise from about 5 vol. % of TWEEN 20, from about 8 vol. % of ethanol, from about 1 vol. % of CPC, about 64 vol. % of oil (e.g., soybean oil), and about 22 vol. % of DiH_2O (designated herein as W_{20}5EC).

[redacted]

Both embodiments are oil-in-water nanoemulsions with a surfactant (TWEEN 80 and TWEEN 20 – same category as Poloxamer 407), a solvent (ethanol – same category as glycerol), and a cationic agent (cetylpyridinium chloride (CPC) – same category as benzalkonium chloride (BZK)). In addition, Example 13 (and corresponding Figures 32 and 33) describes the treatment of Salmonellae with different nanoemulsions of the invention, including $W_{20}5EC$, with the addition of EDTA (tested at 10.0%, 1.0% and 0.1% dilutions).

55. Thus, if NanoBio Protect is determined to satisfy the "HOLD" element (and all elements) of the asserted claims, then the prior art Baker patents necessarily and inherently disclose all elements of the asserted claims as well. In other words, even if the Baker patents do not expressly teach holding the particulate matter in place by adjusting the adhesion and cohesion (or any of the other elements of the asserted claims), the same formulations and compositions described therein inherently would perform those elements as well.

56. With respect to the combination of the Baker patents with one or more of Rolf, Khaled, Rabe, Katz or Wahi '790, I have already explained how each of these secondary references disclose a film or spray containing QACs, including benzalkonium chloride (or equivalent cationic compounds), which a person of skill in the art would understand to inherently have both biocidic properties and cationic properties allowing the compositions to electrostatically attract and kill particulate

[redacted]

matter, even if those particular functions are not expressly described in the references. Nevertheless, I also note that Wahi '790 does expressly disclose a "nasal topical application product for restricting the flow of airborne contaminants into a human nasal passage by creation of a proximate, enhanced electrostatic field." Wahi '790 at Abstract.

VI. CONCLUSION

57. For the aforementioned reasons, in addition to the reasons stated in my Opening Report and Declaration on Claim Construction, in my opinion, to a person of ordinary skill in the art as of the alleged Priority Date of the '802 Patent, each of claims 1, 2, 6 and 7 of the '802 Patent are invalid for each of the reasons explained herein.

Date: September 29, 2022

Respectfully submitted,

Mansoor M. Amiji, Ph.D.

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[redacted]

CERTIFICATE OF SERVICE

I certify that on September 29, 2022, I served the foregoing document and this Certificate of Service on Counsel for Plaintiff via email. A copy is also being mailed via First Class Mail to:

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